UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

CASE NO.:

FILED by RAL D.C.
APR 01 2010
STEVEN M. LARIMORE
CLERK U. S. DIST. CT.
S. D. of FLA. – MIAMI

JACK T. KRAUSER, D.M.D., an individual,

Plaintiff,

v.

BIOHORIZONS, INC., a Delaware corporation, BIOLOK INTERNATIONAL, INC., a Delaware corporation, and BIOHORIZONS IMPLANT SYSTEMS, INC., a Delaware corporation,

Defendants.
_____/

NOTICE OF REMOVAL

Defendants, Biohorizons, Inc., Biolok International, Inc., and Biohorizons Implant Systems, Inc. (collectively "Defendants"), by and through their undersigned counsel, hereby file this Notice of Removal, pursuant to 28 U.S.C. § 1441, removing this action from the Circuit Court for the 15th Judicial Circuit in and for Palm Beach County, Florida, being the District in which this action is pending, and state as follows:

State Court Action

1. This in an action for declaratory relief whereby Plaintiff seeks a declaration of his purported rights, including inventorship rights, to U.S. patents and other related filings, documents and drawings. Plaintiff commenced this action in the Circuit Court of the 15th Judicial Circuit in and for Palm Beach County, Florida, on or about March 4, 2010, and it is now pending before that Court, identified as Case No. 50 2010 CA 000034 XXXX MB (AD). Defendant Biohorizons Implant Systems, Inc. received a copy of the Summons and Amended

Complaint (the "Complaint") on or about March 8, 2010. *See* Summons and Complaint attached hereto as "Exhibit A."

2. The action is one in which the District Court of the United States has original jurisdiction pursuant to 28 U.S.C. § 1332 (a)(1), in that the action is between citizens of different states and the matter in controversy exceeds $75,000, exclusive of interest and costs. All the named Defendants are Delaware corporations with their principal places of business in Alabama. Plaintiff alleges he is a resident of Florida.

3. Also, Plaintiff is seeking declaratory relief relating to the inventorship of various U.S. patents governed by 35 U.S.C. § 256. Therefore, this action arises under federal patent law over which Federal courts have original exclusive jurisdiction. 28 U.S.C. § 1338(a).

4. Defendants have attached to this Notice of Removal, marked as Exhibit A, copies of all process, pleadings, orders and other papers that are on file in the State court, as required by 28 U.S.C. § 1446(a).

5. Notice of filing of this Notice of Removal will be served upon Plaintiff immediately following the filing of this Notice, and a copy of the Notice has been furnished this date to the Clerk of the Circuit Court, 15th Judicial Circuit in and for Palm Beach County, Florida, for filing.

6. By filing this Notice of Removal, Defendants do not waive any defense that may be available to them.

Federal Jurisdiction

7. As set forth above, Plaintiff seeks, *inter alia*, to be declared the inventor of several U.S. patents. As such this action arises under federal patent law, specifically 35 U.S.C. § 256. The Court has jurisdiction over these claims pursuant to 28 U.S.C. § 1331, which states

that, "[t]he district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Moreover, the Court has federal diversity jurisdiction pursuant to 28 U.S.C. § 1332(a)(1).

8. The court has jurisdiction over any remaining claims pursuant to 28 U.S.C. § 1367, and removal is therefore authorized pursuant to 28 U.S.C. § 1441 (c).

Timeliness of Notice of Removal

9. The action was filed on or about March 4, 2010. Defendant Biohorizons Implant Systems, Inc. first received notice of the Complaint on March 8, 21010. Removal of this action is, therefore, timely under 28 U.S.C. § 1446(b).

Relief Requested

10. Defendants request that the United States District Court for the Southern District of Florida, West Palm Beach Division, assume jurisdiction over the above-captioned action and issue such further orders and processes as may be necessary to bring before it all necessary parties.

WHEREFORE, Defendants respectfully requests that this Court assume jurisdiction over the above-captioned action and issue such further orders and processes as may be necessary to bring before it all parties necessary for the trial of this action.

Respectfully submitted,

EDWARDS ANGELL PALMER & DODGE LLP

By: 

Gary A. Woodfield
Florida Bar No. 0563102
Attorneys for Defendants
One Clematis Street, Suite 400
West Palm Beach, FL 33401
Phone: (561) 833-7700
Facsimile: (561) 655-8719
E-mail: gwoodfield@eapdlaw.com

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been furnished by mail this 31st day of March, 2010 to:

Ronald M. Gaché, Esq.
BROAD AND CASSEL
One North Clematis Street, Suite 500
West Palm Beach, Florida 33401

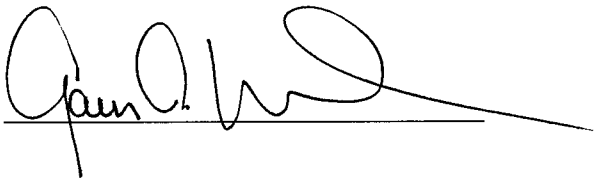


EXHIBIT A

IN THE CIRCUIT COURT OF THE
15th JUDICIAL CIRCUIT IN AND FOR
PALM BEACH COUNTY, FLORIDA

JACK T. KRAUSER, D.M.D.,
an individual,

Plaintiff,

v.

Case No. 50 2010 CA 000034 XXXX MB (AD)

BIOHORIZONS, INC., a Delaware corporation, BIOLOK INTERNATIONAL, INC., a Delaware corporation, and BIOHORIZONS IMPLANT SYSTEMS, INC., a Delaware corporation,

Defendants.
_____/

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SUMMONS

THE STATE OF FLORIDA;
TO EACH SHERIFF OF THE STATE:

You are commanded to serve this Summons and Amended Complaint filed in this matter on the below named Defendant:

BIOHORIZONS IMPLANT SYSTEMS, INC.

c/o its Registered Agent: **NRAI Services, Inc.**
2731 Executive Park Drive, Suite 4
Weston, FL 33331

IMPORTANT

Each Defendant is required to serve written defenses to the Amended Complaint on Plaintiff's attorney, whose address is:

RONALD M. GACHÉ, ESQ.
BROAD AND CASSEL
One North Clematis Street, Suite 500
West Palm Beach, Florida 33401
Tel. No. (561) 832-3300

within **twenty (20) days** after service of this process upon you, exclusive of the day of service, and to file the original of said written answer and defenses with the Clerk of this Court either before service on Plaintiff's attorney or immediately thereafter. If you fail to do so, a default will be entered against you for the relief demanded in the Amended Complaint.

The provisions of § 83.232, Fla. Stat., may apply to this action which requires the tenant to pay into the Registry of the Court accrued rent as alleged or as determined by the Court. "The Court shall notify the tenant of such requirement." Any payment required into the Registry of Court must be cash, cashier's check or money order.

DATED ON MAR 04 2010, 2010.

CLERK OF COURT

(Seal)

KRISTIN BUTLER

By:_____
Deputy Clerk

SHARON R. BOCK
Clerk & Comptroller
P.O. Box 4667
West Palm Beach, Florida
33402-4667

IN THE CIRCUIT COURT OF THE
15th JUDICIAL CIRCUIT IN AND FOR
PALM BEACH COUNTY, FLORIDA

JACK T. KRAUSER, D.M.D.,
an individual,

Plaintiff,

Case No. 50 2010 CA 000034 XXXX MB (AD)

v.

BIOHORIZONS, INC., a Delaware corporation, BIOLOK INTERNATIONAL, INC., a Delaware corporation, and BIOHORIZONS IMPLANT SYSTEMS, INC., a Delaware corporation,

Defendants.
_____/

COPY
RECEIVED FOR FILING
MAR 04 2010
SHARON R. BOCK
CLERK & COMPTROLLER
CIRCUIT CIVIL DIVISION

AMENDED COMPLAINT FOR DECLARATORY RELIEF

The Plaintiff, JACK T. KRAUSER, D.M.D., an individual ("Dr. Krauser" or "Krauser"), sues the Defendants, BIOHORIZONS, INC., a Delaware corporation ("BioHorizons"), BIOLOK INTERNATIONAL, INC., a Delaware corporation ("BioLok"), and BIOHORIZONS IMPLANT SYSTEMS, INC., a Delaware corporation ("BHIS"), and alleges:

PARTIES AND VENUE

1. Dr. Krauser is an individual who resides in Palm Beach County, Florida.

2. BioHorizons is a corporation which is organized and existing under the laws of the State of Delaware.

3. BioHorizons maintains its principal place of business in Birmingham, Alabama.

4. BioLok is a corporation which is organized and existing under the laws of the State of Delaware.

5. According to the records of the Florida Department of State Division of Corporations, BioLok had been authorized to transact business in the State of Florida from August 10, 1993 through September 26, 2008, when its authorization was revoked as a result of its failure to file an annual report, and had maintained its principal place of business in Deerfield Beach, Florida.

6. BHIS is a corporation which is organized and existing under the laws of the State of Delaware.

7. According to the records of the Florida Department of State Division of Corporations, BHIS is authorized to transact business in the State of Florida and maintains its principal place of business in Birmingham, Alabama.

8. In or about 1996, non-party, American BioDental Corporation, a Delaware corporation f/k/a Minimatic Implant Technology, Inc. ("ABC"), merged into BioLok.

9. In or about 1997, non-party, Minimatic Implant Technology, Inc., a Florida corporation f/k/a Minimatic, Inc. ("Minimatic"), merged into BioLok.

10. On or about August 22, 2006, HealthpointCapital, LLC ("Healthpoint"), or one of its affiliates, acquired BHIS.

11. On or about October 31, 2006, Healthpoint, or one of its affiliates, *i.e.*, HealthpointCapital Partners II, L.P., acquired BioLok.

12. On or about February 21, 2008, Healthpoint formed BioHorizons by combining non-party, DTI Dental Technologies, Inc., and BHIS. Upon information and belief, BioHorizons then became the parent company of BHIS.

13. Thereafter, BioHorizons acquired BioLok.

14. Venue for this action is appropriate in Palm Beach County since each of the causes of action alleged herein accrued in Palm Beach County.

GENERAL ALLEGATIONS

Dr. Krauser's Inventions

15. In or around 1987, Dr. Krauser, a world renowned periodontist, first conceived a new particular type of dental implant system containing a longitudinally grooved cylindrical surface, a buttress thread screw and related abutments, components and tooling (the "Dental Implant System").

16. To that end, in or around 1988, Dr. Krauser retained BioLok (then known as Minimatic/ABC), a medical job/machine shop, to produce drawings and manufacture prototypes of his new Dental Implant System, including implants, attachments and related products. At that time, BioLok was not manufacturing or selling any dental implant system of its own.

17. Accordingly, on or about May 17, 1988, Dr. Krauser provided BioLok with all of his initial drawings, work product and intellectual property in connection with his Dental Implant System and paid BioLok the sum of $200.00 as an initial deposit for its services. In turn, BioLok provided Dr. Krauser with a written receipt and invoice for same. Copies of that receipt and invoice are attached collectively hereto as **Exhibit "A."**

18. By early 1991, BioLok had successfully formulated marketable implants, attachments and other products based on Dr. Krauser's Dental Implant System.

19. Moreover, in or about March, 1991, BioLok and Dr. Krauser entered into a royalty agreement (the "1991 Royalty Agreement") whereby BioLok agreed to market and sell Dr. Krauser's new Dental Implant System and pay him commissions of ten percent (10%) of all

of its net sales of his implants and five percent (5%) of its net sales of his attachments and other products.

20. Thus, throughout 1990 and 1991, BioLok (then known as Minimatic/ABC) filed with the U.S. Food and Drug Administration (the "USFDA") its pre-market notifications under Section 510(k) of the Food, Drug and Cosmetic Act of its intent to market and sell to the public Dr. Krauser's new Dental Implant System products. Moreover, because the Dental Implant System has always been in a continuous state of development and refinement up to and including today, BioLok and BioHorizons, as its successor parent, have subsequently filed several other 510(k) registrations to market and sell the Dental Implant System, as modified. Most recently, on October 10, 2007 and November 13, 2008, the USFDA approved BioHorizons' 510(k) nos. K071638 ("BioHorizons Tapered Internal Implant System") and K081818 ("BioLok Micro-Lok Implant System"), respectively. In any event, inasmuch as the Defendants filed all of those 510(k) registrations for the purpose of selling the Dental Implant System, all of them exclusively contained Dr. Krauser's proprietary information. Copies of the USFDA's lists of BioLok's 510(k) registrations referencing the Dental Implant System (reprinted from the USFDA's website) are attached collectively hereto as **Exhibit "B."** Copies of the USFDA's summaries of BioHorizons' 510(k) nos. K071638 and K081818 referencing the Dental Implant System are attached collectively hereto as **Composite Exhibit "C."**

21. However, also in or around February/March, 1991, and unbeknownst to Dr. Krauser at the time, BioLok also submitted to the United States Patent and Trademark Office (the "USPTO") certain disclosure documents wherein it disclosed Dr. Krauser's inventions in

connection with his Dental Implant System, but named itself or its principal, Leon Shaw ("Mr. Shaw"), as the inventor, instead of Dr. Krauser, himself.[1]

22. Then, on June 20, 1991, BioLok (then known as Minimatic/ABC), for the first time, marketed and sold Dr. Krauser's new Dental Implant System to the public at the American Academy of Periodontology 1991 Implant Conference in Washington, D.C. At that time, Dr. Krauser's Dental Implant System was called the Minimatic Implant System, but, in or around 1996 (around the time Minimatic/ABC merged into BioLok), it became commercially known as the BioLok Precision Implant System, and, as of today, it is generally known as the BioHorizons Tapered Internal Implant System, including, without limitation, the tapered Laser-Lok and the mountless TLX series. More specifically, as of today, Dr. Krauser's Dental Implant System includes, without limitation, all tapered internal implants and all prosthetics BioHorizons sells and markets. It does not include BioHorizons' five other types of implants (internal, external, single-stage, one-piece 3.0 and overdenture). To illustrate the difference between Dr. Krauser's products and BioHorizons' other products it developed on its own, copies of certain pages from BioHorizons' Corporate Overview Catalog (found online at www.biohorizons.com/documents/ML0309_BioHorizons_Overview.pdf) describing Dr. Krauser's implants (*i.e.*, "tapered internal") and prosthetics and BioHorizons' five other types of implants are attached hereto as **Exhibit "D."**

[1] As of February 1, 2007, the USPTO eliminated its disclosure document program and now suggests that inventors file provisional applications for patents instead. Under the former program, the USPTO would retain an inventor's disclosure document as evidence of the date of conception of the invention for a period of two years, at which time it would destroy the disclosure document if the inventor had not filed a patent application by that time.

23. Approximately one year later, on June 19, 1992, the very last day prior to the "statutory bar" under 35 U.S.C. 102(b), Dr. Krauser filed with the USPTO his application for a patent on his "dental implant with a longitudinally grooved cylindrical surface."[2]

24. Approximately two years later, on or about May 31, 1994, Dr. Krauser obtained his patent, Patent No. 5,316,476 (the "Patent" or "476 Patent"), from the USPTO. A copy of the 476 Patent is attached hereto as **Exhibit "E."**

Parties' Prior Litigation

25. Meanwhile, by 1993, while BioLok had been manufacturing and selling Dr. Krauser's Dental Implant System, it had failed to pay Dr. Krauser amounts due as his commissions under their 1991 Royalty Agreement.

26. As a result, on or about July 8, 1993, Dr. Krauser initiated in this court the case styled *Jack T. Krauser, et al. v. Leon Shaw and Minimatic Implant Technology, Inc., etc.*, Case No. 50 1993 CA 005862 XXOC AJ (the "State Court Action"), wherein he sought, among other things, the recovery of monetary damages against BioLok (then known as Minimatic/ABC) and a declaration of his ownership rights in and to the Dental Implant System.

27. Moreover, on or about September 8, 1994, or shortly after he obtained his Patent, Dr. Krauser also initiated in the United States District Court for the Southern District of Florida the case styled *Jack T. Krauser, et al. v. Minimatic Implant Technology, Inc., et al.*, Case No. 94-CV-08521-ASG (the "Federal Court Action"), wherein he asserted, among other things, claims

[2] 35 U.S.C. 102(b) provides: "A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States." Like many inventors, Dr. Krauser purposely waited until the last possible day before the statutory bar to file his application for a patent on his invention so as to maximize the time period covered by the patent.

for patent and copyright infringement against BioLok (then known as Minimatic/ABC) in connection with their unauthorized use of his 476 Patent and sale of his Dental Implant System.

28. In fact, on or about February 12, 1993 and December 27, 1993, respectively, unbeknownst to Dr. Krauser at the time, BioLok and/or its principal, Mr. Shaw, improperly filed its own applications for patents on a so-called "dental implant system" and "buttress thread implant," which were based entirely on Dr. Krauser's inventions, ideas, drawings and other intellectual property, including, for that matter, many internal aspects of his 476 Patent, without even referencing Dr. Krauser as the inventor.[3]

29. In turn, on or about May 16, 1995 and October 12, 1999, BioLok and/or Mr. Shaw actually obtained those Patents Nos. 5,415,545 ("dental implant system") and 5,964,766 ("buttress thread implant") from the USPTO. Copies of those two patents are attached collectively hereto as part of **Composite Exhibit "F."**

30. Then, to make matters worse, beginning in 1999, BioLok (or its successors) filed applications for and obtained several other patents also based on Dr. Krauser's inventions, ideas, drawings and other intellectual property, including, without limitation, much of the subject matter of his 476 Patent, such as its Patent No. 6,149,432 ("buttress thread dental implant"), Patent No. 6,375,464 ("micromechanical seal for dental implant systems"), Patent No. 6,406,296 ("implant with enlarged proximal segment"), Patent No. 6,419,491 ("dental implant system with repeating micro geometric surface patterns"), Patent No. 6,454,569 ("dental implant having a dual bio-affinity collar") and Patent No. 6,648,643 ("dental implant/abutment interface and

[3] Not only did BioLok base its patent applications on Dr. Krauser's work product, it filed its applications more than one year after it had begun marketing and selling the Dental Implant System in June, 1991, in violation of 35 U.S.C. 102(b), and, with respect to at least one of those applications, more than two years after it had filed its disclosure documents in or around February/March, 1991, in violation of the USPTO's disclosure document program then in effect.

system having prong and channel interconnections"), all without referencing Dr. Krauser as the inventor. Copies of each of those patents are also attached collectively hereto as part of **Composite Exhibit "F."**

31. Incidentally, during the pendency of the Federal Court Action, upon BioLok's and Mr. Shaw's request, the USPTO conducted a re-examination of Dr. Krauser's 476 Patent. On June 18, 1996, after it completed its investigation, the USPTO issued a Re-Examination Certificate confirming the patentability of Dr. Krauser's inventions described in his Patent. In particular, the USPTO stated: "NO AMENDMENTS HAVE BEEN MADE TO THE PATENT. AS A RESULT OF RE-EXAMINATION, IT HAS BEEN DETERMINED THAT: The patentability of claims 1-23 [set forth in the 476 Patent] is confirmed." (capitals in original) A copy of that Re-Examination Certificate is attached hereto as the last three pages of **Exhibit "E"** after the initial 476 Patent.

32. Also during the pendency of the State Court Action and the Federal Court Action, on or about January 10, 1996 and April 2, 1996, BioLok (then known as Minimatic/ABC) filed its voluntary petitions under Chapter 11 in the United States Bankruptcy Court for the Southern District of Florida (the "Bankruptcy Court") in consolidated Cases Nos. 96-30109-SHF and 96-31318-SHF (collectively, the "Bankruptcy Case").

33. In that Bankruptcy Case, Dr. Krauser timely filed several prepetition claims against BioLok, including his claims related to those he had asserted in the State Court Action and the Federal Court Action.

34. Shortly thereafter, on or about May 28, 1996, in order to resolve all pending claims, disputes and litigation between them, BioLok and Dr. Krauser (and others) entered into a

Settlement Agreement (the "May 1996 Settlement Agreement"). A copy of that May 1996 Settlement Agreement (without exhibits) is attached hereto as **Exhibit "G."**

35. In the May 1996 Settlement Agreement, BioLok (then known as Minimatic/ABC) specifically acknowledged:

> The board of directors of Minimatic/ABC does not contest Krauser's ownership of the [476] Patent for a cylindrical implant design which is sold and described in Minimatic/ABC's current catalog and recognizes same as valid, being subject only to the claimed defense of shop-rights and associated shop-right defenses under applicable law. The parties hereto acknowledge that Krauser maintains that no such shop-rights exist and that the [476] Patent is free of all defenses whatsoever. Moreover, Minimatic/ABC hereby waive any and all other defenses they may have to Krauser's enforcement of the [476] Patent. (p. 23, ¶ 17).
>
> The board of directors of Minimatic/ABC does hereby recognize Krauser's significant individual contribution to the invention and creation of what is today known as the "Minimatic Implant System" in concept, design, design application, ease of installation and overall system requirements. The board of directors of Minimatic/ABC also hereby recognize that without Krauser's contribution, it is unlikely that the current product line would have ever been developed or would have ever reached the market place. (p. 24, ¶ 18).

36. Moreover, by their individual execution of the May 1996 Settlement Agreement, all of the members of the board of directors of Minimatic/ABC, including its then President and CEO, Bruce Hollander, "unanimously approved" and adopted the May 1996 Settlement Agreement as written action of the board of directors. (May 1996 Settlement Agreement, p. 37).

37. That said, while the Bankruptcy Court never formally approved the May 1996 Settlement Agreement, BioLok's foregoing acknowledgments therein remain in full force and effect and "may be used in any proceeding between these parties" under the express terms thereof. (May 1996 Settlement Agreement, p. 32, ¶ 30).

38. As a result, on the same date it entered into the May 1996 Settlement Agreement, May 28, 1996, BioLok voluntarily dismissed, *with prejudice*, all counterclaims it had asserted against Dr. Krauser in the State Court Action.

October 1996 Settlement Agreement

39. Ultimately, on or about October 16, 1996, BioLok and Dr. Krauser (and others) entered into another Settlement Agreement (the "October 1996 Settlement Agreement"). A copy of that October 1996 Settlement Agreement (without exhibits) is attached hereto as **Exhibit "H."**

40. On or about November 5, 1996, BioLok filed with the Bankruptcy Court its Motion to Approve the October 1996 Settlement Agreement and, on or about November 26, 1996, the Bankruptcy Court entered its Order Granting Motion to Approve the October 1996 Settlement Agreement.

41. Approximately three months later, on or about February 12, 1997, the Bankruptcy Court entered its Order Confirming Joint Second Amended Chapter 11 Plan (the "Amended Plan"), which incorporated the parties' October 1996 Settlement Agreement.

42. Under the terms of the October 1996 Settlement Agreement, Dr. Krauser conditionally granted to BioLok for a term of ten (10) years from the date of confirmation of its Amended Plan in the Bankruptcy Case, *i.e.*, February 12, 1997 through February 11, 2007, (a) his rights in his 476 Patent and (b) an exclusive license to manufacture, use and sell his Dental Implant System (then commercially known as the Minimatic Implant System or BioLok Precision Implant System, which subsequently evolved into the BioHorizons Tapered Internal Implant System, including, without limitation, the tapered Laser-Lok and the mountless TLX series), which incorporated his inventions, ideas, drawings and other intellectual property, including, without limitation, much of the subject matter of his 476 Patent. To that end, Dr.

Krauser conditionally granted to BioLok "any and all rights he may have in the Patent and the dental implant system currently being manufactured by the Debtors" and agreed to forego asserting his rights in his Dental Implant System, so long as BioLok complied with all of its obligations under the October 1996 Settlement Agreement. (October 1996 Settlement Agreement, p. 5, ¶¶ 2, 3).

43. Dr. Krauser further agreed that, at the end of the ten-year term, in the event BioLok had fully complied with all of its obligations under the October 1996 Settlement Agreement (including all payment and accounting obligations set forth therein), he would unconditionally assign to it all of his rights in and to his Patent and Dental Implant System. (October 1996 Settlement Agreement, p. 5, ¶ 2).

44. However, the parties also agreed that, in the event BioLok defaulted under any of the terms of the October 1996 Settlement Agreement, the conditional license would automatically terminate and Dr. Krauser would be entitled to enforce all of his rights and remedies in connection with his ownership of his Patent and Dental Implant System, including, but not limited to, injunctive relief. (October 1996 Settlement Agreement, p. 5, ¶ 2). In particular, in the event of BioLok's default, Dr. Krauser would "have the option, but not the obligation, to institute suit against [BioLok] for money damages and/or ***a declaration of his rights in and to the dental implant system currently being manufactured by the Debtors, as well as any and all 510(k) filings, related documents and drawings of the Debtors***." (October 1996 Settlement Agreement, p. 11, ¶ 8) (emphasis added).

45. Paragraph 7 of the October 1996 Settlement Agreement specifically defined an "event of default" so as to include the following:

> (1) The failure of Minimatic or ABC to pay Krauser, at the time said payments are due, or in the amount called for herein, any of the sums required by this Settlement Agreement to be paid to him, however, Minimatic/ABC shall be entitled to five (5) business days' written notice thereof by telecopier at (954) 698-9925 and/or regular mail to Minimatic/ABC's business premises to cure any such default; [or]
>
> (2) The failure to Minimatic or ABC to comply with any of the provisions of this Settlement Agreement or the terms of the Debtors' Amended Plan as it pertains to Krauser, and in the case of their failure to comply with a non-monetary provision of this Settlement Agreement, their failure to cure such non-compliance following ten (10) business days after their receipt of written notification by telecopier at (954) 698-9925 and/or regular mail to Minimatic/ABC's business premises from Krauser specifying the non-compliance.
>
> (October 1996 Settlement Agreement, pp. 10-11, ¶ 7).

46. Paragraph 3 of the October 1996 Settlement Agreement provided that BioLok's obligations under the Settlement Agreement "will not be diminished nor eliminated in any manner by [its] merger into, or acquisition by, any other entity, and any such successor entity will remain liable to Krauser for all obligations set forth in this Settlement Agreement, unless otherwise agreed to by Krauser, whose agreement to same may be unreasonably withheld." (October 1996 Settlement Agreement, p. 8, ¶ 3). Moreover, Paragraph 16 further provided that "[t]his Settlement Agreement shall be binding on all of the parties hereto, including each of their successors and assigns, specifically including any successor corporation to either Minimatic and/or ABC, or any subsidiary thereof, and Krauser." (October 1996 Settlement Agreement, p. 14, ¶ 16).

47. Thus, there is no question the October 1996 Settlement Agreement is binding not only upon BioLok as the successor by merger to Minimatic/ABC, but also upon BioHorizons and BHIS as its successors, assigns or subsidiaries. (*See, also,* October 1996 Settlement

Agreement, pp. 6, 7, ¶ 3 ("the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquisition")).

48. As consideration for Dr. Krauser's conditional grant of his rights to his Patent and license to manufacture, use and sell his Dental Implant System, BioLok agreed to pay royalties to Dr. Krauser during the ten-year term of the October 1996 Settlement Agreement. In particular, during years 3 through 10 following the Bankruptcy Court's confirmation of BioLok's Amended Plan on February 12, 1997, *i.e.*, from February 12, 2000 through February 11, 2007, BioLok agreed to pay Dr. Krauser royalties in the sum of "2% of all total net sales by the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquisition of the Products,[4] irrespective of the net sales amount." (October 1996 Settlement Agreement, p. 7, ¶ 3(b)).

49. With regard to the time BioLok was required to pay Dr. Krauser his royalty payments, Paragraph 4 of the October 1996 Settlement Agreement provided that "[a]ll of the foregoing payments identified in paragraph 3 above shall be paid to Krauser on the 15th day of each month in arrears... every month irrespective of the sales amount for years 3 through 10." (October 1996 Settlement Agreement, p. 8, ¶ 4).

50. The October 1996 Settlement Agreement also required that BioLok produce monthly sales reports with its monthly payments to Dr. Krauser as follows:

[4] "Net sales" is defined in the October 1996 Settlement Agreement as "all gross sales from the Products less only returns, discounts (including discounts to customers, distributors and agents), credits given in lieu of returns and freight and handling charges, if applicable, and nothing else." (October 1996 Settlement Agreement, p. 7, ¶ 3). "Products" is defined as "all dental implant products set forth and described in the Debtors' current product catalog..., as well as any other dental implant products of any kind or nature whatsoever which are designed and/or used for dental implantology which are sold by the Debtors, any subsidiary thereof or any successor owner of the Debtors by merger or acquisition, now or in the future, whether they be listed for sale or not in any current or future Minimatic, ABC, any subsidiary's thereof or any successor owner of the Debtors by merger or acquisition, catalog." (October 1996 Settlement Agreement, p. 6, ¶ 3(a)(i)).

> In order to ensure that Krauser will be timely paid all amounts called for in paragraph 3 above, Minimatic/ABC shall furnish to Krauser, on a monthly basis, a complete and accurate sales report evidencing the total net sales of the Products for that preceding month.... Said monthly sales reports shall be delivered to Krauser each and every month, and... shall be accompanied by the royalty payment due in connection therewith.
>
> (October 1996 Settlement Agreement, p. 9, ¶ 4).

51. Moreover, the October 1996 Settlement Agreement also required that BioLok maintain adequate books and records and allow Dr. Krauser and his accountants, upon their request, to inspect and conduct an audit of those books and records. In particular, Paragraph 5 of the October 1996 Settlement Agreement stated:

> Minimatic/ABC will keep adequate records and books of accounts in accordance with generally accepted accounting principles evidencing all sales and deliveries of the Products and all income or other consideration received as a result of the sale or delivery of the Products. Following the giving of reasonable notice, Krauser and his accountants will be entitled to visit and inspect the business premises of Minimatic/ABC (or any other place where Minimatic/ABC's financial records may be kept in the ordinary course of business) and examine Minimatic/ABC's records and books of accounts as they relate to gross and/or net sales of the Products at such reasonable times as Krauser and the Debtors shall agree not to exceed one time per each quarter in any given fiscal year.
>
> (October 1996 Settlement Agreement, pp. 9, ¶ 5).

Defendants' Defaults under Settlement Agreement

52. Inasmuch as the parties had entered into their October 1996 Settlement Agreement, the Defendants have continued, to this day, to manufacture, use and sell Dr. Krauser's Dental Implant System (now commercially known as the BioHorizons Tapered Internal Implant System, including, without limitation, the tapered Laser-Lok and the mountless TLX series), which fully incorporates his inventions, ideas, drawings and other intellectual

property, including, without limitation, much of the subject matter of his 476 Patent. *See*, Exhibit D (BioHorizons' catalog).

53. However, notwithstanding their obligations under the October 1996 Settlement Agreement, the Defendants, during the entire ten-year term of Dr. Krauser's conditional grant of his rights and license thereunder (and since then, given the Defendants' further obligations as a result of the termination of the conditional rights and license), have continuously failed to timely (a) pay Dr. Krauser amounts due under the Settlement Agreement, (b) provide sales reports and account to him in the manner set forth in the Settlement Agreement and (c) allow him and his accountants to inspect and conduct an audit of their books and records.

54. To that end, on August 6, 2009, after Dr. Krauser had made several prior demands for payment of royalties due under the October 1996 Settlement Agreement, BioHorizons' President and CEO, Steve Boggan ("Mr. Boggan"), emailed him and advised him:

> We completed an extensive review of the amounts owed to you per your previous agreement with BioLok. We included all sales of BioLok implants including MicroLok and Silhouette. In addition, this agreement was selected for audit by Ernst and Young so the numbers should be exact. The analysis shows that we owe you $103,226.75 which will complete all obligations of BioLok and BioHorizons as indicated in the agreement. I assume that this will resolve all open matters that we have with you. Please let me know if you prefer a check or wire transfer for the amounts owed. [emphasis added]

A copy of Mr. Boggan's August 6, 2009 email is attached hereto as **Exhibit "I."**

55. Approximately one month later, on September 1, 2009, after Dr. Krauser had made several additional demands for sales reports and an accounting and requested an audit as provided under the October 1996 Settlement Agreement, BioHorizons' Executive Vice President and CFO, Kendyl D. Lowe ("Ms. Lowe"), emailed him and advised him:

> We have collected the publically-filed audited sales of BioLok International Inc. for the ten-year time period covered by the royalty agreement. I will have it all summarized and compiled to send to you tomorrow. I apologize for not getting back to you sooner. I just didn't want you to think we weren't working on your request for data.

A copy of Ms. Lowe's September 1, 2009 email is attached hereto as **Exhibit "J."**

56. Thereafter, BioHorizons never provided Dr. Krauser with its monthly sales reports or proper payments due under the October 1996 Settlement Agreement or authorized him (and his accountants) to conduct an audit of its book and records as set forth under the October 1996 Settlement Agreement.

57. That said, Dr. Krauser disputes BioHorizons' calculations of the royalties the Defendants never paid him.

58. For that reason, on October 1, 2009, Dr. Krauser initiated in this court the case styled *Jack T. Krauser, D.M.D. v. Minimatic Implant Technology, Inc., etc.*, Case No. 2009 CA 033368 XXXX MB AA (the "2009 Action"), wherein he asserted, among other things, claims for breach of contract and declaratory relief based on the Defendants' breach of the October 1996 Settlement Agreement.

59. Two weeks later, on October 15, 2009, in light of the Defendants' assertion in the 2009 Action that Dr. Krauser had failed to serve them with a proper notice of default under the October 1996 Settlement Agreement, and notwithstanding his many prior demands for payments, sales reports and an audit (as well as his 2009 Complaint, which also served as his notice of default), Dr. Krauser, through his attorneys, Gonzalez & Henley, P.L. ("Gonzalez & Henley"), personally served the Defendants with two additional notices of their defaults under the Settlement Agreement (one referencing his "Declaration of Regaining Ownership Rights in

Dental Implant System and License Termination" and one referencing his "Demand for Audit") and actually filed both of those notices with the court in the 2009 Action. Copies of those two notices of default are attached collectively hereto as **Composite Exhibit "K."**

60. Moreover, two months later, on or about December 14, 2009, Gonzalez & Henley, in an extreme abundance of caution, filed Dr. Krauser's Notice of Voluntary Dismissal Without Prejudice in the 2009 Action and, on that very same day, served the Defendants, both directly and through their attorney, with yet another notice of their defaults in failing to make payments, provide sales reports and authorize an audit, all as required under the express terms of the October 1996 Settlement Agreement.[5] A copy of Gonzalez & Henley's December 14, 2009 notice of default is attached hereto as **Exhibit "L."**

61. Shortly thereafter, on or about December 22, 2009, BioHorizons sent Dr. Krauser its check no. 006611 in the sum of $71,780.83 as its purported "full and final payment." A copy of that check is attached hereto **Exhibit "M."**

62. One week later, on or about December 29, 2009, Gonzalez & Henley provided the Defendants with still another notice demanding that they cure their defaults under the October 1996 Settlement Agreement. A copy of Gonzalez & Henley's December 29, 2009 notice of default (without exhibits) is attached hereto as **Exhibit "N."**

63. However, because the Defendants have failed to cure their monetary and non-monetary defaults within five (5) days and ten (10) days, respectively, pursuant to the terms of the October 1996 Settlement Agreement, and have still failed to (a) pay Dr. Krauser the full amount of the royalties they owe him, (b) provide him with proper monthly sales reports or (c)

[5] Incidentally, Dr. Krauser also attempted to fax his notice of default to the Defendants at the fax number set forth in the October 1996 Settlement Agreement, 954-698-9925, but that number is no longer in service.

authorize him (and his accountants) to conduct an audit of their books and records, he has elected not to deposit BioHorizons' insufficient check and, instead, exercise his express right under the October 1996 Settlement Agreement to sue the Defendants for "***a declaration of his rights in and to the dental implant system currently being manufactured by the Debtors, as well as any and all 510(k) filings, related documents and drawings of the Debtors.***"[6] (October 1996 Settlement Agreement, p. 11, ¶ 8).

DECLARATORY RELIEF

64. This is a cause of action for declaratory relief under Florida Statues, Chapter 86, pertaining to the parties' rights, duties and obligations under the terms of the October 1996 Settlement Agreement and the parties' rights to Dr. Krauser's 476 Patent and Dental Implant System. The amount in controversy exceeds $15,000.00, exclusive of costs, interest and attorneys' fees.

65. Dr. Krauser realleges and incorporates paragraphs 1 through 63 as if same were more fully set forth herein.

66. Because the Defendants have defaulted under the express terms of the October 1996 Settlement Agreement by failing to timely pay Dr. Krauser all amounts they owe him thereunder, and have failed to cure that monetary default within the time period set forth therein, the conditional license Dr. Krauser granted them to manufacture, use and sell his Dental Implant System incorporating his inventions set forth in his Patent has terminated, and he maintains the

[6] While Dr. Krauser, at this time, is only seeking a declaration of his rights in and to his dental implant system and related matter, he is not waiving, and specifically reserves, any and all of his other rights and remedies he maintains under the October 1996 Settlement Agreement, Florida law and/or Federal law as a result of the Defendants' misconduct, including, without limitation, his right to sue the Defendants' for monetary damages and patent infringement.

right to a declaration of his rights in and to his Dental Implant System, as well as any and all related 510(k) filings, documents and drawings.

67. Because the Defendants have defaulted under the express terms of the October 1996 Settlement Agreement by failing to timely provide Dr. Krauser with proper sales reports as required thereunder, and have failed to cure that non-monetary default within the time period set forth therein, the conditional license Dr. Krauser granted them to manufacture, use and sell his Dental Implant System incorporating his inventions set forth in his Patent has terminated, and he maintains the right to a declaration of his rights in and to his Dental Implant System, as well as any and all related 510(k) filings, documents and drawings.

68. Because the Defendants have defaulted under the express terms of the October 1996 Settlement Agreement by failing to allow Dr. Krauser and his accountants to inspect and conduct an audit of their books and records as set forth thereunder, and have failed to cure that non-monetary default within the time period set forth therein, the conditional license Dr. Krauser granted them to manufacture, use and sell his Dental Implant System incorporating his inventions set forth in his Patent has terminated, and he maintains the right to a declaration of his rights in and to his Dental Implant System, as well as any and all related 510(k) filings, documents and drawings.

69. Nevertheless, the Defendants maintain they have complied with their obligations under the October 1996 Settlement Agreement and Dr. Krauser has unconditionally assigned to them all of his rights in and to his Patent and Dental Implant System.

70. As a result, the parties have a legitimate, present, continuing and bona fide dispute as to their rights, duties and obligations under the terms of the October 1996 Settlement Agreement and their rights to Dr. Krauser's 476 Patent and Dental Implant System.

71. All conditions precedent to the institution of this action have occurred, been met or otherwise been waived.

72. Dr. Krauser has retained the undersigned attorneys to represent him in this action and has agreed to pay them a reasonable fee for their services rendered, which fee he is entitled to recover from the Defendants pursuant to the terms of the October 1996 Settlement Agreement.

WHEREFORE, Dr. Krauser demands that the court enter a declaratory judgment as follows:

a. construing the terms of the October 1996 Settlement Agreement;

b. finding and declaring that the Defendants defaulted under the terms of the October 1996 Settlement Agreement by failing to timely pay him all amounts they owe him thereunder;

c. finding and declaring that the Defendants defaulted under the terms of the October 1996 Settlement Agreement by failing to timely provide him with sales reports as required thereunder;

d. finding and declaring that the Defendants defaulted under the terms of the October 1996 Settlement Agreement by failing to allow him and his accountants to inspect and conduct an audit of their books and records as set forth therein;

e. finding and declaring that the Defendants failed to cure their monetary and non-monetary defaults within the applicable time periods set forth in the October 1996 Settlement Agreement after he provided them with written notice of their defaults;

f. finding and declaring that the conditional license he granted them under the October 1996 Settlement Agreement to manufacture, use and sell his Dental Implant System has terminated;

g. finding and declaring that he is the inventor and owner of the subject matter set forth in all of the Defendants' patents based on his 476 Patent, including, without limitation, all patents set forth in Composite Exhibit "F" hereto;

h. finding and declaring that he is the inventor and owner of the subject matter set forth in all of the Defendants' 510(k) registrations based on his 476 Patent, including, without limitation, all 510(k) registrations set forth in Exhibit "B" and Composite Exhibit "C" hereto;

i. finding and declaring that he is the inventor and owner of the Dental Implant System, now commercially known as the BioHorizons Tapered Internal Implant System, including, without limitation, the tapered Laser-Lok and the mountless TLX series, as well as any and all related 510(k) filings, documents and drawings;

j. awarding him his attorneys' fees and costs he has incurred, and will incur, in connection with this matter pursuant to the terms of the October 1996 Settlement Agreement (p. 12, ¶ 15); and

k. granting such other and further relief as the court deems just and proper.

Dated: March 4, 2010

BROAD AND CASSEL
Attorneys for Jack T. Krauser, D.M.D.
One North Clematis Street, Suite 500
West Palm Beach, Florida 33401
Telephone: (561) 832-3300
Facsimile: (561) 655-1109

By: _____
Ronald M. Gaché, Esq.
Florida Bar No. 699306
Scott A. Simon, Esq.
Florida Bar No. 0088676

Minimatic, Inc.
MANUFACTURERS OF PRECISION MACHINE PRODUCTS
AND MEDICAL DEVICES
580 S. MILITARY TRAIL
DEERFIELD BEACH, FL 33442
TELEPHONE (305) 421-9300
FAX (305) 428-1578



May 17, 1988

Received from Jack T. Krauser, D.M.D

deposit of $200.00 for drawings of

implant.

INVOICE

No. [illegible]

MINIMATIC INC.
398 MILITARY TRAIL • DEERFIELD BEACH, FLORIDA 33442
P.O. Box 9408
TELEPHONE 305 421-9300
FAX NUMBER: 305 428-1578

Dr. Jack Krauser
2499 West Glades Rd
Boca Raton, FL 33431

INVOICE DATE: 5/18/83
OUR ORDER NO.:
YOUR ORDER NO.:
TERMS: F.O.B.:
SALESPERSON:
SHIPPED VIA:
PPD OR COLL.

QUANTITY	DESCRIPTION	PRICE	AMOUNT
	Drawings of Implant		200.00

A 1-1/2% INTEREST CHARGE PER MONTH, TOTAL 18% per year on all invoices over 30 days past due.
ALL CLAIMS MUST BE MADE 10 DAYS AFTER RECEIPT OF GOODS.
This is to certify that the merchandise listed in this invoice has been produced in accordance with the fair labor standards act of 1938, as amended

We put cash money into Petty via John Cotugno

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PLAINTIFF'S EXHIBIT "B"

510(k) Premarket Notification

510 (k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

35 records meeting your search criteria returned - **Applicant:** *Minimatic*

New Search Export to Excel | Download Files | More About 510(k)

Device	Applicant	510 (k)	Decision Date
Minimatic Various Implant Systems	Minimatic, Inc.	K952905	04/16/1997
Dpi-1106 Implant, Modification	Minimatic Implant Technology	K911776	01/15/1992
Hh-1119 Healing Head	Minimatic Implant Technology	K903515	07/04/1991
Device Part Numbers: - 1400 Series	Minimatic Implant Technology	K911112	06/10/1991
Implant, Threaded External Hex, Tapered	Minimatic Implant Technology	K905039	04/29/1991
Bc 1208 Implant, Threaded External Hex	Minimatic Implant Technology	K904707	04/29/1991
Ict-1108 Implant- Threaded (Cement Type	Minimatic Implant Technology	K903043	04/19/1991
Idt-1104 Implant (Screw-In-Threaded)	Minimatic Implant Technology	K903046	04/19/1991
Bc 1206 Implant - Insert Type	Minimatic Implant Technology	K904705	04/12/1991
Bc 1219 Healing Head	Minimatic Implant Technology	K904710	03/29/1991
Bc 1221 Ball Overdenture Attachment	Minimatic Implant Technology	K904712	03/29/1991
Bc 1203 Abutment Tapered Shoulder	Minimatic Implant Technology	K904704	03/21/1991
Bc 1207 Abutment Fixed	Minimatic Implant Technology	K904706	03/21/1991

Bc 1211 Abutment, Fixed Transfer Pin, In	Minimatic Implant Technology	K904708	03/21/1991
Bc 1213 Healing Screw	Minimatic Implant Technology	K904709	03/21/1991
Bc-1201 Cast Abutment	Minimatic Implant Technology	K904703	03/15/1991
Device Part Number Dpi-1106 Implant	Minimatic Implant Technology	K902928	01/29/1991
Bc 1220 Analog - Implant Body	Minimatic Implant Technology	K904711	01/14/1991
Cga-112 Coping Gold Alloy	Minimatic Implant Technology	K903113	12/27/1990
A-1101 Cast Abutment	Minimatic Implant Technology	K903039	12/26/1990
A-1107 Abutment (Fixed)	Minimatic Implant Technology	K903041	11/30/1990
A-1103 Abutment (Removable)	Minimatic Implant Technology	K903040	11/26/1990
Device Part Number: Svd-3s Drill	Minimatic Implant Technology	K902930	11/20/1990
Tc-1111 Transfer Pin	Minimatic Implant Technology	K903044	11/20/1990
Abo-1122 Analog Ball Overdenture	Minimatic Implant Technology	K903518	11/20/1990
Satc-1114, Shoulder Abutment Transfer Co	Minimatic Implant Technology	K904460	11/20/1990
Aa-1110 Analog Abutment	Minimatic Implant Technology	K903042	11/13/1990
Hs-1113 Healing Screw - Rev. A	Minimatic Implant Technology	K903062	11/13/1990
Pp-1105 Parallel Pin	Minimatic Implant Technology	K903114	11/13/1990
Aib-1120 Analog-Implant Body	Minimatic Implant Technology	K903517	11/13/1990
Device Part Number: Pd-12 Pilot Drill	Minimatic Implant Technology	K902931	11/13/1990
Part Number: Ta-1118 Tap	Minimatic Implant Technology	K903112	11/13/1990
Bo-1121 Ball Overdenture Attachment	Minimatic Implant Technology	K903516	11/13/1990

Device Part Number Svd2, 3, 4 Spade Dril	Minimatic Implant Technology	K902929	11/13/1990
Dg-1109 Depth Gage	Minimatic Implant Technology	K903115	11/13/1990

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510(k) Premarket Notification



510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

2 records meeting your search criteria returned - **ProductCode:** *DZE* **Applicant:** *Bio-Lok*

New Search Export to Excel | Download Files | More About 510(k)

Device	Applicant	510(k)	Decision Date
Modification To Silhouette Ic Or Silhoue	Bio-Lok Intl., Inc.	K041136	10/22/2004
Silhouette(Tm) Ic Or Silhouette(Tm) & La	Bio-Lok Intl., Inc.	K032454	03/04/2004

K071638

510(k) Summary

OCT 10 2007



BioHorizons Implant Systems, Inc.
BioHorizons Tapered Internal Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name:	BioHorizons Implant Systems, Inc. One Perimeter Park South, Suite 230 South Birmingham, AL 35243 USA Telephone 1 (205) 967-7880 Fax 1 (205) 870-0304
Official Contact:	Winston Greer
Representative/Consultant:	Linda Schulz or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone 1 (858) 792-1235 Fax 1 (858) 792-1236 email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BioHorizons Tapered Internal Implant System
Common Name:	Dental implants and abutments
Classification Regulations:	Endosseous dental implant (21 CFR 872.3640), Class II Endosseous dental implant abutment (21 CFR 872.3630), Class II
Product Codes	DZE, NHA

DEVICE CLASSIFICATION PANEL

The Classification Panel for these devices is the Dental Products Panel, and they are reviewed by the Dental Devices Branch.

INTENDED USE

The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention.

The BioHorizons Tapered Internal Implant System may be restored immediately

1) with a temporary prosthesis that is not in functional occlusion or
2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

DEVICE DESCRIPTION

BioHorizons Tapered Internal Implant System is a system of tapered, threaded, internal connection, root form implants and matching abutments intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The external design of the implant is the same as that of the Bio-Lok Implant System, including the Laser-Lok® collar. The internal connection and the platform are the same as those of the BioHorizons Prodigy System™ Endosseous Implants.

EQUIVALENCE TO MARKETED PRODUCT

BioHorizons Implants Systems, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the BioHorizons Tapered Internal Implant System is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

BioHorizons Implant Systems, Incorporated
C/O Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
11234 EL Camino Real, Suite 200
San Diego, California 92130

Re: K071638
Trade/Device Name: BioHorizons Tapered Internal Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 26, 2007
Received: September 27, 2007

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071638

Device Name: BioHorizons Tapered Internal Implant System

Indications for Use:

The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention.

The BioHorizons Tapered Internal Implant System may be restored immediately
1) with a temporary prosthesis that is not in functional occlusion or
2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K071638

K081818

510(k) Summary
21 CFR 807.92

NOV 13 2008

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
2300 Riverchase Center
Birmingham, AL 35244
Phone: (205) 967-7880
Fax: (205) 870-0304
Official contact: Michael Davis, Regulatory Affairs Specialist
Date prepared: June 25, 2008

Name of the Device

Trade Name:	BioLok Micro-Lok Implant System
Common or Usual Name:	Screw-type Dental Implants
Classification Name:	Endosseous implants, surgical components, and prosthetic attachments
Classification Number:	Class II

Predicate Device

The Minimatic (BioLok International) Various Implant Systems, documented under 510(k) number K952905, concurrence date of April 16, 1997.

Device Description

The BioHorizons BioLok Micro-Lok dental implants are machined titanium, root-form implants supplied in 3.45mm, 3.75mm, 4mm, and 4.75mm diameters across lengths of 8mm, 10mm, 11.5mm, 13mm, and 15mm. Implant and accessory surgical component raw material is titanium alloy as specified in ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6}, validated in compliance to ANSI/AAMI/ISO 11137, *Sterilization of healthcare products - Requirements for validation and routine control - Radiation Sterilization.*

Intended Use

The intended use of the BioHorizons BioLok Micro-Lok endosseous implants is in the mandible and maxilla as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

Technological Characteristics

The fundamental scientific technology of the device is identical to the referenced predicate device. All materials and specifications (with the exception of the particular ASTM standard titanium specified in the original 510(k) submission), processing and sterilization methods remain the same as for the predicate Minimatic endosseous implants. The material has not changed to a type that has not been used in other legally marketed devices within the same classification regulation for the same intended use. The BioHorizons BioLok Micro-Lok implants are substantially equivalent to all features of the predicate Minimatic (BioLok International) Various Implant System device which could affect safety or effectiveness because of the similarities in design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

Mr. Michael Davis
Regulatory Affairs Specialist
BioHorizons Implant Systems, Incorporated
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K081818
Trade/Device Name: BioLok Micro-Lok Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 10, 2008
Received: October 14, 2008

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Brigitte G. Mickum OMD.
FOR DR. CHIU LIN

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K081818

Device Name: BioLok Micro-Lok Implant System

Indications for Use:

The BioLok Micro-Lok Implant System may be used in edentulous sites for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or partial dentures, or a single tooth replacement, overdenture, or hybrid denture.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

Susan Runner

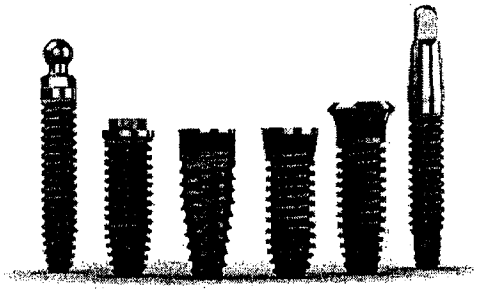
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

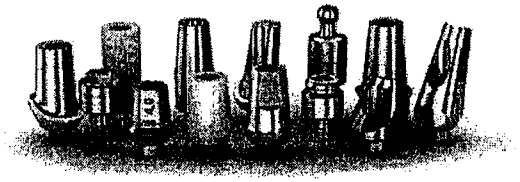
510(k) Number: K081818

improving the lives of patients

BIOHORIZONS®

SCIENCE • INNOVATION • SERVICE





dental implants

BioHorizons offers six comprehensive implant lines, covering virtually every surgical and prosthetic indication or clinician preference. Our implants carry an unconditional lifetime warranty, and are clinically proven through some of the most thorough and in-depth research in the industry.

prosthetics

BioHorizons implants come with two different yet intuitive connections, the internal and external hex. Both have been shown over decades of use to provide a stable, secure connection with tight tolerance machining that establishes a biologic seal. We offer a broad array of prosthetics in either connection for a wide range of indications and patient conditions.

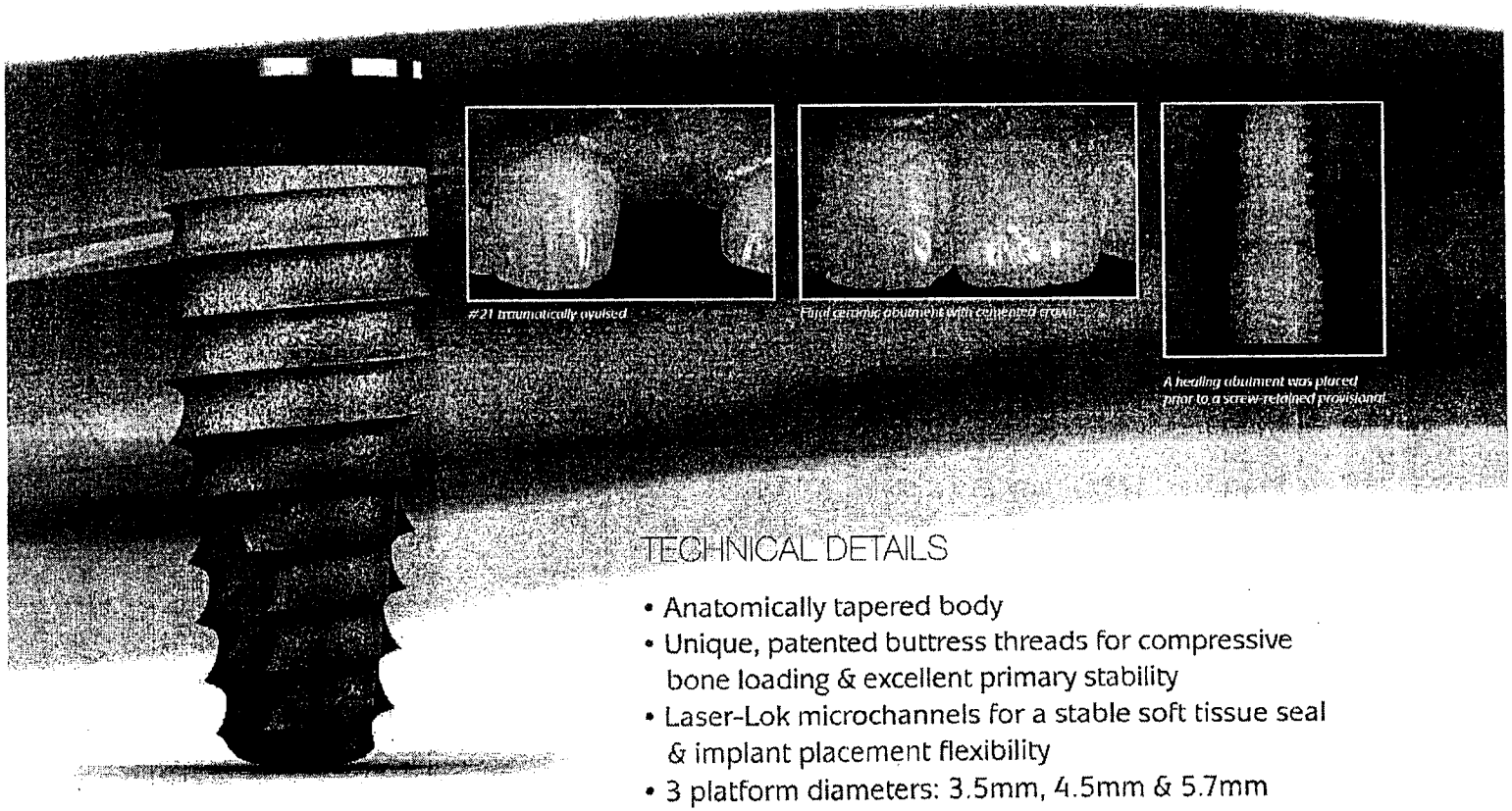
it's about innovative solutions that work.

From surgical planning and site development to final restoration, BioHorizons is uniquely positioned to streamline the implant to restorative process, enabling clinicians to create a more efficient and effective continuum of care.

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tapered internal

Designed for clinicians who prefer a tapered implant, the Tapered Internal is all about high-end, esthetic performance and is the "flagship" of the BioHorizons implant line. With its aggressive buttress thread and tapered apical six millimeters, the Tapered Internal achieves high initial torque values and excellent primary stability. The Laser-Lok collar and uniquely-designed drills give clinicians the flexibility to select the ideal implant level for optimal esthetics.



Case courtesy of Craig Misch, DDS
Sarasota, Florida

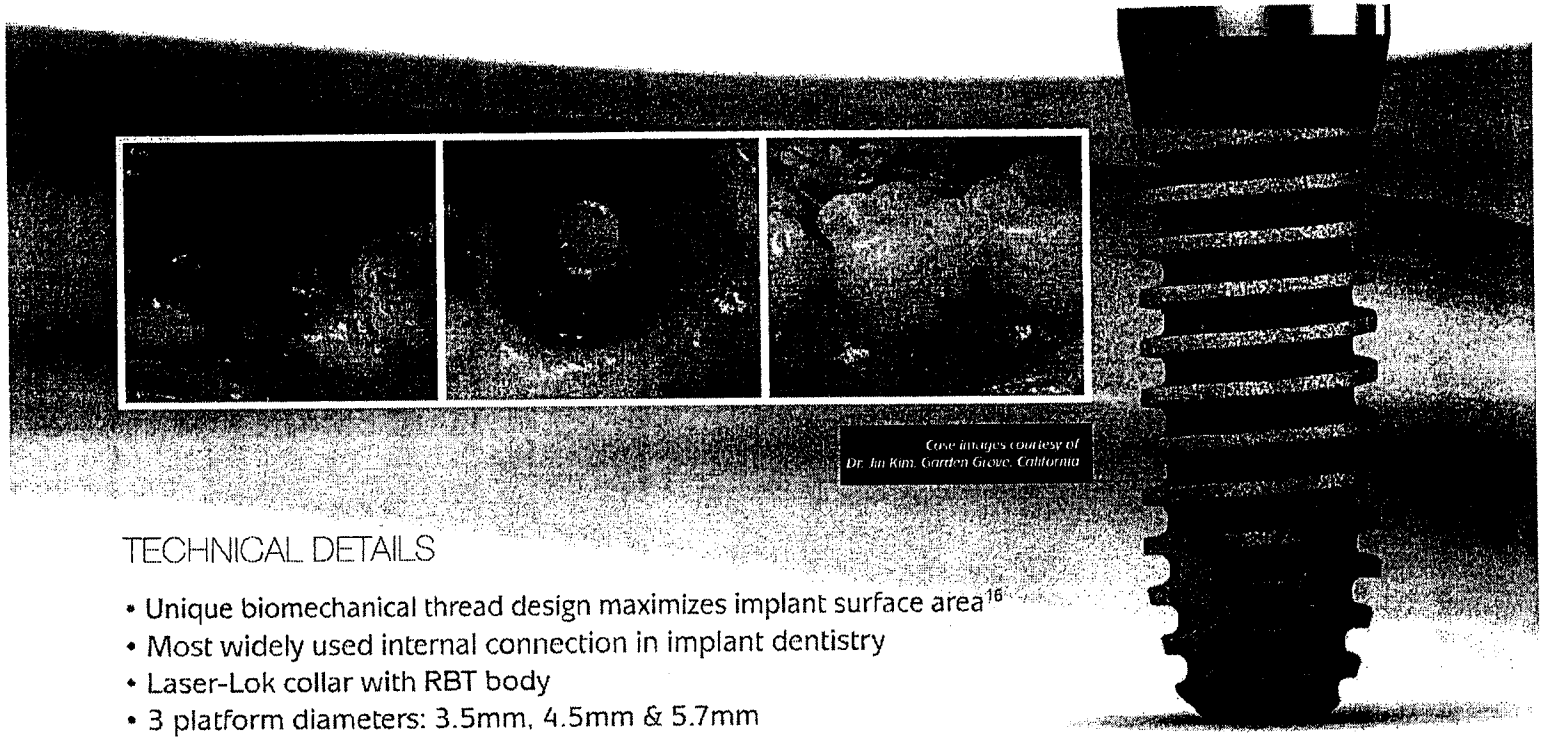
TECHNICAL DETAILS

- Anatomically tapered body
- Unique, patented buttress threads for compressive bone loading & excellent primary stability
- Laser-Lok microchannels for a stable soft tissue seal & implant placement flexibility
- 3 platform diameters: 3.5mm, 4.5mm & 5.7mm
- 5 lengths: 7.5mm, 9mm, 10.5mm, 12mm & 15mm

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internal

Launched in 2004, the Internal implant quickly became BioHorizons' most popular implant design as many dentists shifted their preferences towards internal connections. With the same basic shape and thread design as the External, the Internal leverages all of the External's science and research to assure clinicians achieve successful outcomes.



Cone images courtesy of Dr. Jin Kim, Garden Grove, California

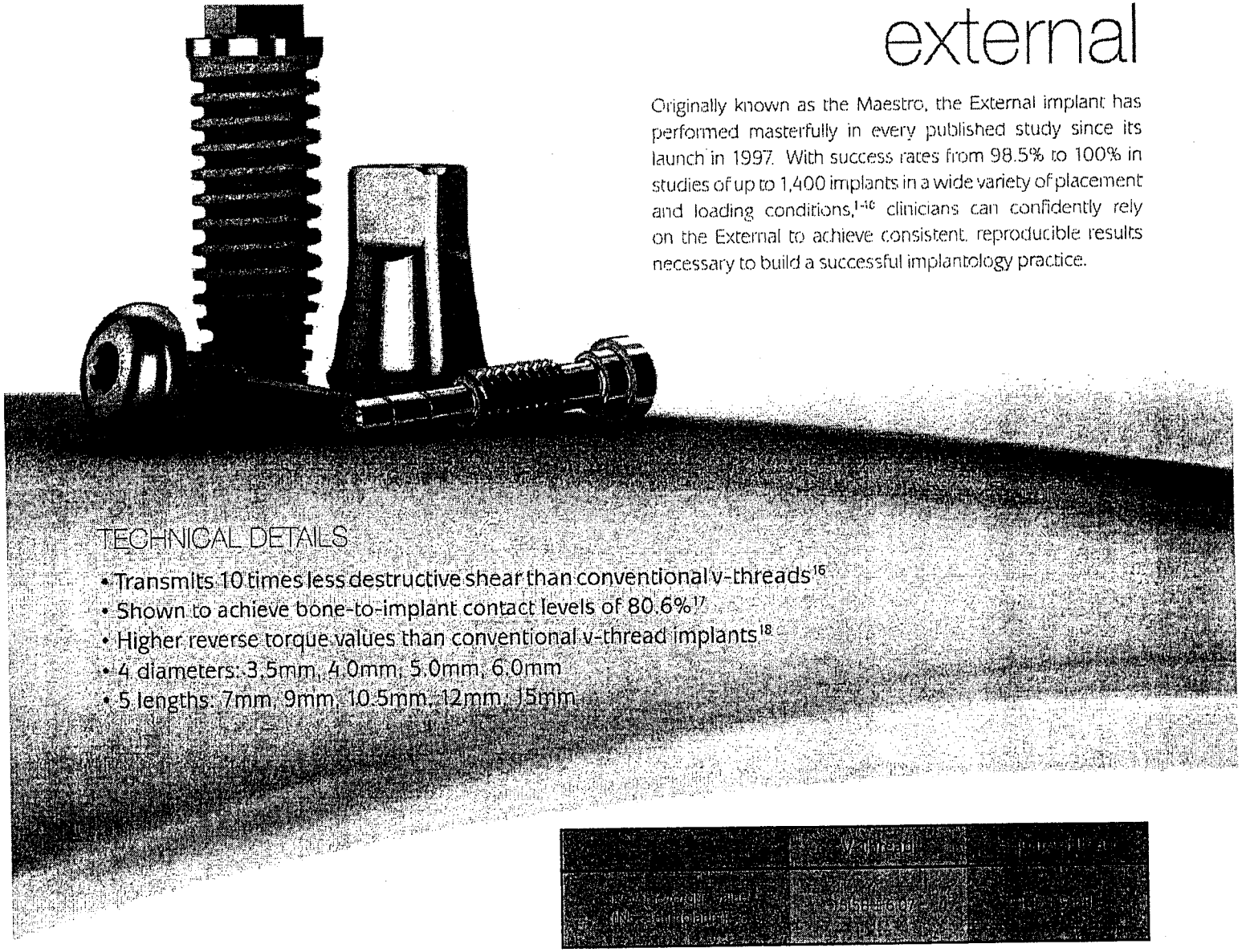
TECHNICAL DETAILS

- Unique biomechanical thread design maximizes implant surface area[16]
- Most widely used internal connection in implant dentistry
- Laser-Lok collar with RBT body
- 3 platform diameters: 3.5mm, 4.5mm & 5.7mm
- 4 lengths: 9mm, 10.5mm, 12mm, 15mm

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external

Originally known as the Maestro, the External implant has performed masterfully in every published study since its launch in 1997. With success rates from 98.5% to 100% in studies of up to 1,400 implants in a wide variety of placement and loading conditions,[1-16] clinicians can confidently rely on the External to achieve consistent, reproducible results necessary to build a successful implantology practice.



TECHNICAL DETAILS

- Transmits 10 times less destructive shear than conventional v-threads[16]
- Shown to achieve bone-to-implant contact levels of 80.6%[17]
- Higher reverse torque values than conventional v-thread implants[18]
- 4 diameters: 3.5mm, 4.0mm, 5.0mm, 6.0mm
- 5 lengths: 7mm, 9mm, 10.5mm, 12mm, 15mm

	V-thread	
	[illegible]	

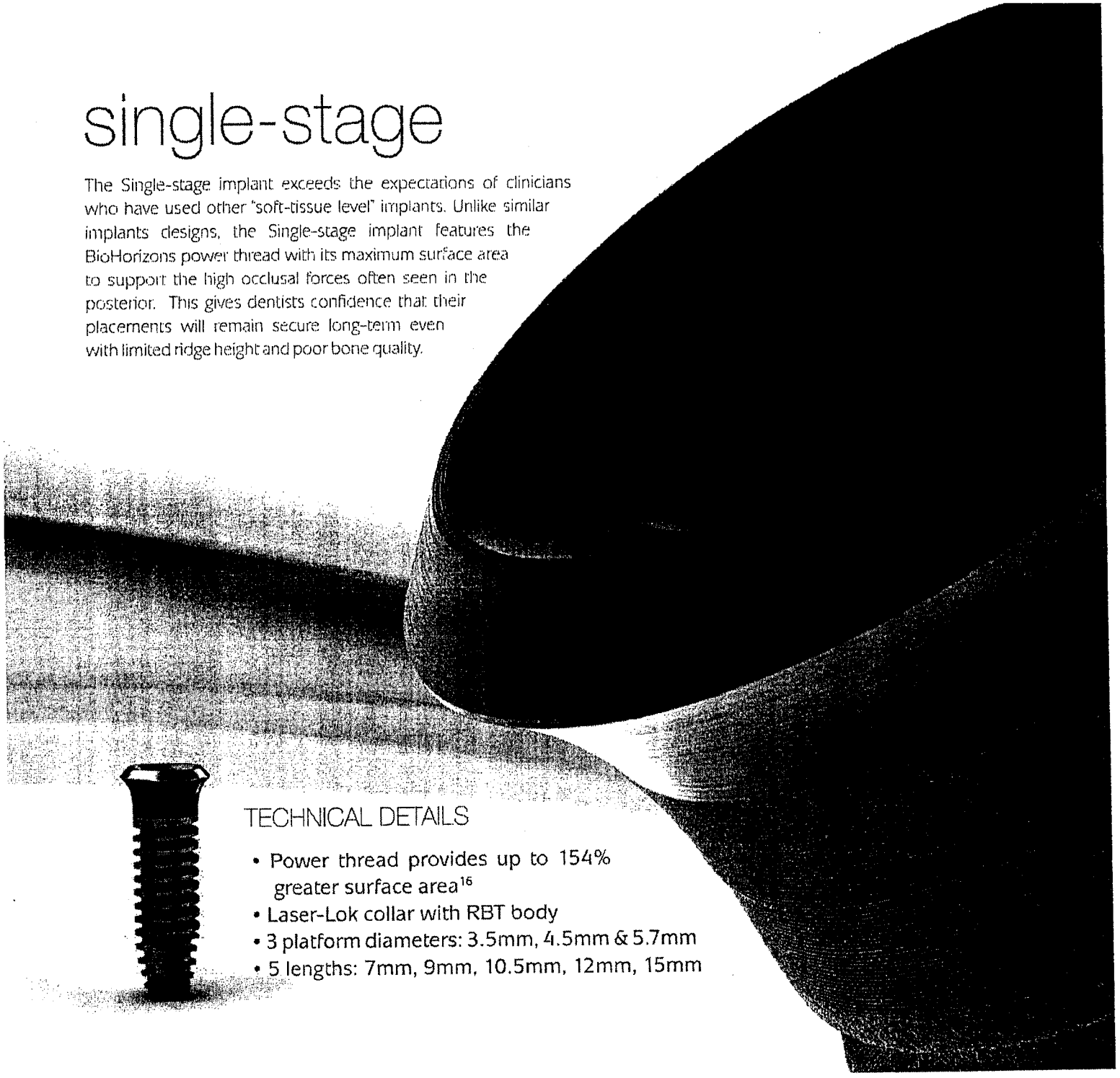
Table 1. Reverse torque removal values in Ncm (N = 12 rabbits).*

* Statistical significance ($P < 0.05$) when comparing square thread to V-thread and reverse buttress thread design.

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single-stage

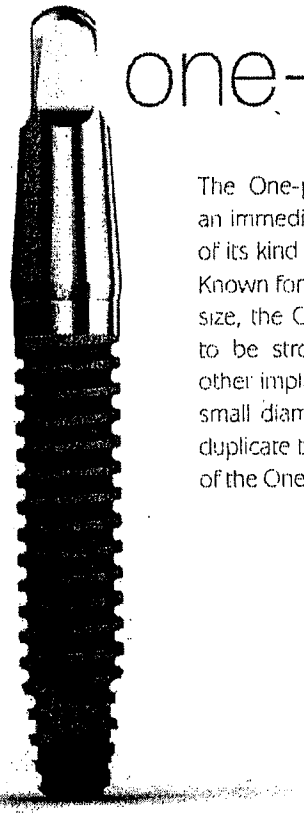
The Single-stage implant exceeds the expectations of clinicians who have used other "soft-tissue level" implants. Unlike similar implants designs, the Single-stage implant features the BioHorizons power thread with its maximum surface area to support the high occlusal forces often seen in the posterior. This gives dentists confidence that their placements will remain secure long-term even with limited ridge height and poor bone quality.



TECHNICAL DETAILS

- Power thread provides up to 154% greater surface area[16]
- Laser-Lok collar with RBT body
- 3 platform diameters: 3.5mm, 4.5mm & 5.7mm
- 5 lengths: 7mm, 9mm, 10.5mm, 12mm, 15mm

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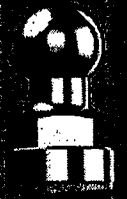


one-piece 3.0

The One-piece 3.0 (aka Maximus) was an immediate success as the first implant of its kind when it was launched in 2003. Known for its amazing strength despite its size, the One-piece 3.0 has been shown to be stronger in "load to failure" than other implants less than 4mm.[19] No other small diameter implant has been able to duplicate the strength and clinical success of the One-piece 3.0.

TECHNICAL DETAILS

- Indicated for long-term replacement of missing maxillary laterals and mandibular incisors
- Shown to achieve an overall survival rate of 96.7 percent[4]
- Stronger than other implants less than 4mm[19]



overdenture

Specifically designed for long-term denture stabilization, the Overdenture replaces the gold-hued esthetic top of the One-piece 3.0 with an integrated ball abutment. Each implant comes packaged with everything needed for chairside denture pick-up. Minimal instrumentation is required to place either system.

- Specifically indicated for long-term denture stabilization
- Biomechanical square thread design proven to have high stability and increase bone-to-implant contact
- One-piece design provides maximum strength and restorative simplicity

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