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

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.

CASE NO.: 9:10 CV 80454-MARRA

DECLARATION OF HEATHER S. ROSECRANS IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I, HEATHER S. ROSECRANS, hereby declare as follows:

1. I submit this declaration in support of Defendants BioHorizons, Inc., Bio-Lok International, Inc. and BioHorizons Implant Systems, Inc.'s (collectively "BioHorizons") motion for summary judgment.

2. I am a Senior Advisor for Regulatory Affairs at Greenleaf Health, LLC, a full service regulatory consulting firm that provides guidance to healthcare sector clients, including pharmaceutical, biotechnology, and medical device companies whose activities are regulated by FDA. I am also the Vice President of Regulatory Affairs for the Medical Device Manufacturers Association, a national trade association that provides educational and advocacy assistance to innovative and entrepreneurial medical technology companies, particularly smaller companies.

3. A "Summary of Accomplishments" prepared prior to my retiring from FDA is attached to this declaration as Exhibit A.

4. I received a B.S. in Biology from Pfeiffer College in 1976.

5. I joined FDA in July of 1977 and worked at the National Center for Antibiotic Analysis. In December of 1978 I moved to the FDA's Bureau of Medical Devices' ("BMD") (now the Center for Devices and Radiological Health ("CDRH")) Premarket Evaluation Group in the Microbiology Branch as a reviewer. In that role, I reviewed Premarket Notification Submissions ("510(k)s") and Premarket Approval Applications ("PMAs"), organized and participated in meetings of the Microbiology Devices Advisory Panel, prepared letters to manufactures regarding submissions, applications, and final decision letters, and drafted proposed microbiology classification device regulations (21 C.F.R. § 866).

6. In 1987, I joined the 510(k) Staff of the Program Operations Staff within the Office of Device Evaluation at CDRH. In that role, I also served as a Consumer Safety Officer. My responsibilities included drafting regulations, drafting guidance documents, and training staff, in addition to drafting, coordinating and overseeing the administrative, scientific, and regulatory review process for 510(k)s. I played a key role in implementing the Medical Device User Fee Modernization Act, the Food and Drug Administration Modernization Act, and the Safe Medical Devices Act of 1990, specifically in regard to the 510(k) Program.

7. In 1992, I became Acting Chief of the 510(k) Staff; in 1993, that promotion became permanent, with the position subsequently becoming known as Director of the CDRH 510(k) Staff. In that role, I supervised the administrative, regulatory and policy review of 510(k) submissions, 513(g) requests, reclassification petitions, and petitions for exemption from premarket regulatory requirements. Additionally, I directed the Premarket Notification (510(k)) Program for FDA's Office of In Vitro Diagnostic Device Evaluation and Safety once that office became separate from the Office of Device Evaluation.

8. While at FDA, I was nationally and internationally recognized as FDA's most senior expert in regulatory and policy matters relating to the 510(k) program. As such, I was frequently consulted by CDRH staff and senior management, officials in other FDA Centers, FDA's Office of General Council, FDA's Office of Combination Products, FDA's Office of Regulatory Affairs, as well as

external agencies such as the Government Accountability Office, when complex and/or controversial questions arose in the 510(k) area.

I. FDA PREMARKET REVIEW OF MEDICAL DEVICES

9. Historically, the Food and Drug Administration had only limited authority to act with respect to devices. *See S.* Rep. No. 94-33 (1975) at 2. On May 28,1976, President Gerald Ford signed into law the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 ("the 1976 Act"). The 1976 Act amended the Federal Food, Drug, and Cosmetic Act so as to provide FDA with significant new authority to provide reasonable assurance of the safety and effectiveness of devices intended for human use. *See generally* Establishment Registration and Premarket Notification Procedures, 41 Fed. Reg. 37458 (Sept. 3, 1976).

10. The 1976 Act amended, among other provisions, Section 510 of the Federal Food, Drug, and Cosmetic Act so as to require manufacturers and other specified producers of medical devices to register each year with FDA and to provide FDA with a list of all medical device types manufactured in any establishment that they own.

11. The 1976 Act added a new subsection, Section 510(k), to the registration provisions of the Federal Food, Drug, and Cosmetic Act. Section 510(k) requires any person who proposes to begin the introduction into interstate commerce for commercial distribution of a device intended for human use to notify FDA at least 90 days in advance of such introduction. This notification is generally known as a "510(k)."

12. The Federal Food, Drug, and Cosmetic Act requires FDA to classify devices into one of three categories: Class I (general controls), Class II (special controls), or Class III (premarket approval). *See* 21 U.S.C. § 360(c). These classes correspond to various levels of oversight for medical devices, depending upon the risks the devices present and how well the mitigation of those risks is understood. Class I, which includes such device types as elastic

bandages and examination gloves, is subject to "general controls" such as labeling requirements, adverse event reporting, and prohibitions on misbranding and adulteration. Most Class I device types are exempt from the 510(k) requirements of the FD&C Act under section 510(1) of the Act. Class II, which includes such device types as sutures and dialysis equipment, is subject to "special controls" such as performance standards and post market surveillance measures, in addition to general controls. Most Class II device types are also subject to 510(k) requirements. Class III devices, such as mechanical heart valves and coronary stents, are subject to a rigorous premarket approval ("PMA") process to demonstrate safety and effectiveness for the intended use. That process typically includes studies and investigations of the device's safety and effectiveness. *See generally Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (describing the various classes of devices).

13. A device not in commercial distribution prior to May 28, 1976, is automatically classified in Class III, unless FDA determines by review of a 510(k) that the device is of the same type as, and is "substantially equivalent" to a device type on the market before May 28, 1976, or a subsequently legally marketed device that is not subject to premarket approval. *See* 21 C.F.R. 807.92(a)(3).

14. If FDA determines, via the notification required by Section 510(k), that a device which a company proposes to market is (a) "substantially equivalent" to a device legally marketed prior to May 28, 1976, or is (b) "substantially equivalent" to a device marketed subsequently to May 28, 1976 and that is not subject to premarket approval, 21 C.F.R. 807.92(a)(3), FDA must notify the manufacturer promptly that the device described in the 510(k) is substantially equivalent and marketing may commence.

15. If FDA determines that a device which a manufacturer proposes to market is not (a) "substantially equivalent" to a device marketed prior to May 28, 1976, or (b) "substantially equivalent" to a device marketed subsequent to May 28, 1976, and not subject to premarket approval, the device is determined to be not substantially equivalent and cannot be marketed until it (a) complies with the premarket approval requirements of Section 515 of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 360e), (b) is reclassified into Class I (general controls) or Class II (performance standards), (c) a de novo petition under section 513(f)(2) of the Act is approved., or (d) the device is subsequently determined to be "substantially equivalent" in a new 510(k).

16. If FDA determines that the new device is substantially equivalent ("SE") to a legally marketed predicate device, FDA will issue an order declaring as much. *See* 21 C.F.R. 807.100. Such an order is variously known as a "510(k) SE letter" or a "510(k) clearance letter".

II. A 510(k) CLEARANCE NEITHER CONVEYS NOR ESTABLISHES INTELLECTUAL PROPERTY

17. FDA's order declaring the new device described in a 510(k) to be substantially equivalent to a legally marketed predicate device, i.e., a 510(k) clearance, is a determination that permits legal marketing of the proposed device, as described in the 510(k), in the United States, subject, of course, to other requirements of the Act such as labeling and the Good Manufacturing process. *See* Medical Devices, 57 Fed. Reg. 58400, 58401 (Dec. 10, 1992) (adopting regulations mandated by the 1990 Act). There may also be other Federal or State laws that apply. FDA's substantial equivalence order conveys no right or power to exclude others from marketing the same or similar devices through a substantial equivalence determination for their own 51(k).

18. FDA review of 510(k)s routinely rely on predicate devices designed and legally marketed by other companies. Indeed, FDA helps 510(k) submitters identify substantially

equivalent devices through maintenance of databases and regulatory mechanisms. *See, e.g.*, Strengthening the CDRH's 510(k) Review Process, 75 Fed. Reg. 4402,4406 (Jan. 27, 2010). And FDA generally does not treat as confidential data or information submitted with, or incorporated by reference in, a premarket notification (other than safety and effectiveness data that have not been disclosed to the public) once the intent to market the proposed device is no longer confidential. See 21 C.P.R. 807.95. Thus, large portions of a 510(k) will be available through a combination of the FDA's databases and Freedom of Information requests (and hence may be used by competitors to develop competing devices) once the device that is the subject of the 510(k) is marketed. See generally 21 C.F.R. Pt. 20.

19. For example, a submitter may demonstrate substantial equivalence by directly copying a legally marketed medical device, including a medical device developed and legally marketed by another.

20. A company could even obtain its own 510(k) clearance by photocopying another company's cleared 510(k) and submitting it under its own name.

21. As the foregoing shows, the custom and practice in the medical device industry is that a device manufacturer is free to submit a 510(k) based in whole or in part on another manufacturer's device(s). Derivation and reliance on an earlier legally marketed device does not alter the ownership of a 510(k), which belongs to the company that holds the 510(k) clearance, not the holder of the 510(k) for the predicate device. Any exclusionary rights would depend upon whatever patents the parties owned, but such rights do not affect the 510(k) process itself.

III. INDUSTRY STANDARD FDA POLICY ON OWNERSHIP OF 510(k)S

22. FDA policy for determining the owner of a 510(k) is clear: a 510(k) submitter/holder is the owner of the 510(k). *See Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (Aug. 12, 2005).

23. Although a consultant or correspondent may submit the 510(k) and accompanying documents on behalf of the 510(k) owner, that consultant or correspondent is not the 510(k) submitter/holder. See id.

24. Ownership of a 510(k) is determined by the identification in the cover letter of the 510(k) of who is submitting the 510(k) or, if a consultant prepares the 510(k), for whom the 510(k) is being submitted, unless all parties involved request (in writing) a change prior to clearance. The FDA's 510(k) database reflects the 510(k) holder as of the date of clearance.

25. Only a single entity may own a 510(k).

26. Only a single entity may use a specific 510(k) number as authorization for their marketing unless the 510(k) number is used pursuant to one of the exceptions listed in 21 CFR § 807.85.

27. A 510(k) may be bought, sold, or transferred. See, e.g., Strengthening the CDRH's 510(k) Review Process; 75 Fed. Reg. 4402, 4406 (Jan. 27, 2010); Guidance for Industry and FDA Staff: Medical Glove Guidance Manual (Jan. 22, 2008) (FDA Document No. 1661).

28. When a 510(k) is bought, sold, or transferred, the new owner of a 510(k) must maintain information documenting the transfer of ownership of a 510(k), including any legal transactions that took place, in its 510(k) files. See 21 U.S.C. §§ 351, 352. It is the responsibility of the new owner to maintain files with documentation proving ownership of the 510(k). See, e.g., Guidance for Industry and FDA Staff: Medical Glove Guidance Manual (Jan. 22, 2008) (FDA Document No. 1661).

29. The new owner of a transferred 510(k) must list the device according to 21 C.F.R. Part 807 and the previous owner must delete its device listing for that 510(k). See id.

30. FDA may request a review of documentation of ownership of a 510(k). See, e.g., Guidance for Industry and FDA Staff: Medical Glove Guidance Manual (Jan. 22, 2008) (FDA Document No. 1661) (available http://www.fda.gov). If FDA deems the documentation of transfer to be inadequate, the transferee will not have clearance to legally market the device(s) covered by that 510(k) clearance.

31. As noted above, a device may be changed or modified without submission of a new 510(k) only so long as the change or modification could not significantly affect safety or effectiveness as per 21 CFR 807.81(a)(3). But if a 510(k) holder modified the device after receiving 510(k) clearance, and did not submit a new 510(k) because it incorrectly viewed the change or modification as not significant, the existing 510(k) clearance may not be legally sufficient to allow commercial distribution of the modified device. For this reason, it is industry practice for a contract transferring 510(k) ownership to include provisions that expressly disclose all modifications made subsequent to receiving the 510(k) clearance. See Jeffrey K. Shapiro, How to Transfer Ownership of a 510(k) Clearance or PMA Approval in Regulatory Affairs Focus 32-34 (Apr. 2000). The absence of such a provision in a contract would be a strong indication (absent an express provision to the contrary) that the contract was not intended to transfer ownership of a 510(k).

32. FDA regulations require extensive record-keeping by device manufacturers. See generally 21 C.F.R. Parts 803, 806, 807, 820. FDA may request to review those records. If FDA deems the records inadequate, the manufacturer may not be able to legally market the device(s) covered by those records. Thus, it is standard industry practice that a contract providing for transfer of 510(k) ownership explicitly provide for transfer of all required records as well. See Jeffrey K. Shapiro, How to Transfer Ownership of a 510(k) Clearance or PMA Approval in

Regulatory Affairs Focus 32-34 (Apr. 2000). The absence of such a provision would be a strong indication (absent an express provision t the contrary) that the contract was not intended to transfer ownership of a 510(k).

IV. ORIGINAL OWNERSHIP ANALYSIS OF SPECIFIC MINIMATIC 510(k)s

33. I have reviewed materials related to each of the 510(k)s and the resulting 510(k) clearances identified in Dr. Krauser's Amended Proof of Claim, as well as materials related to the additional 510(k)s identified in Exhibit B to Dr. Krauser's Second Amended Complaint. For each of these 510(k)s, I also reviewed the associated entry in FDA's 510(k) database.

510(k) CLEARANCE No. K903039/A (PART No. 1101)

34. The 510(k) which resulted in 510(k) clearance K903039/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

35. Based on FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that FDA understood that ownership of 510(k) clearance K903039/A resided with Minimatic Implant Technology, Inc.

36. Consistent with my conclusion, FDA 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903039. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on December 26, 1990.

510(k) CLEARANCE No. K903113/A (PART No. 1102)

37. FDA's responsive correspondence suggests that the 510(k) which resulted in 510(k) clearance K903113/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

38. Based on FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that FDA understood that ownership of 510(k) clearance K903113/A resided with Minimatic Implant Technology, Inc.

39. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903113. The database further states that the 510(k) was received by FDA on July 13, 1990, and was cleared on December 27, 1990.

510(k) CLEARANCE No. K903040/A (PART No. 1104)

40. The 510(k) which resulted in 510(k) clearance K903040/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

41. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903040/A resided with Minimatic Implant Technology, Inc.

42. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903040. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on November 26, 1990.

510(k) CLEARANCE No. K903046/B (PART No. 1104)

43. The 510(k) which resulted in 510(k) clearance K903046/B was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

44. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903046/B resided with Minimatic Implant Technology, Inc.

45. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the holder for 510(k) No. K903046. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on April 19, 1991.

510(k) CLEARANCE No. K903114/A (PART No. 1105)

46. The 510(k) which resulted in 510(k) clearance K903114/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

47. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903114/A resided with Minimatic Implant Technology, Inc.

48. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the holder for 510(k) No. K903114. The database further states that the 510(k) was received by FDA on July 13, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K902928/B (PART No. 1106)

49. The 510(k) which resulted in 510(k) clearance K902928/B was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

50. Leon Shaw's letter of January 3, 1991, referencing 510(k) K902928, identifies Dr. Jack Krauser as a "professional consultant" and notes that a letter submitted by Dr. Krauser was "via our authority". This letter is consistent with industry practice and indicates that Minimatic Implant Technology, Inc. owned the subject 510(k) notification and the resulting clearance, K902928/B.

51. Dr. Jack Krauser's letter of December 24, 1990, referencing 510(k) number K902928, identifies Dr. Krauser as a "Consultant to Minimatic Implant Technologies Incorporated" and carbon copies Leon Shaw in his capacity as President of Minimatic Implant Technologies, Inc. This letter is consistent with industry practice and indicates that Minimatic Implant Technology, Inc. owned the subject 510(k) notification and the resulting clearance, K902928/B.

52. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K902928/B resided with Minimatic Implant Technology, Inc.

53. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the holder for 510(k) No. K902928. The database further states that the 510(k) was received by FDA on July 3, 1990, and was cleared on January 29, 1991.

510(k) CLEARANCE No. K903041 (PART No. 1107)

54. The 510(k) which resulted in 510(k) clearance K903041/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

55. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903041/A resided with Minimatic Implant Technology, Inc.

56. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the holder for 510(k) No. K903041. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on November 30, 1990.

510(k) CLEARANCE No. K903043/B (PART No. 1108)

57. The 510(k) which resulted in 510(k) clearance K903043/B was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

58. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903043/B resided with Minimatic Implant Technology, Inc.

59. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903043. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on April 19, 1991.

510(k) CLEARANCE No. K903115/A (PART No. 1109)

60. The 510(k) which resulted in 510(k) clearance K903115/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

61. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903115/A resided with Minimatic Implant Technology, Inc.

62. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903115. The database further states that the 510(k) was received by FDA on July 13, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K903042/A (PART No. 1110)

63. The 510(k) which resulted in 510(k) clearance K903042/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

64. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903042/A resided with Minimatic Implant Technology, Inc.

65. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903042. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K903044/A (PART No. 1111)

66. The 510(k) which resulted in 510(k) clearance K903044/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

67. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903044/A resided with Minimatic Implant Technology, Inc.

68. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903044. The database further states that the 510(k) was received by FDA on July 11, 1990, and was cleared on November 20, 1990.

510(k) CLEARANCE No. K903062/A (PART No. 1113)

69. The 510(k) which resulted in 510(k) clearance K903062/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

70. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903062/A resided with Minimatic Implant Technology, Inc.

71. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903062. The database further states that the 510(k) was received by FDA on July 9, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K904460 (PART No. 1114)

72. The 510(k) which resulted in 510(k) clearance K904460 was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

73. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904460 resided with Minimatic Implant Technology, Inc.

74. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904460. The database further states that the 510(k) was received by FDA on October 1, 1990, and was cleared on November 20, 1990.

510(k) CLEARANCE No. K903112/A (PART No. 1118)

75. The 510(k) which resulted in 510(k) clearance K903112/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

76. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903112/A resided with Minimatic Implant Technology, Inc.

77. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903113. The database further states that the 510(k) was received by FDA on July 13, 1990, and was cleared on December 27, 1990.

510(k) CLEARANCE No. K903517/A (PART No. 1120)

78. The 510(k) which resulted in 510(k) clearance K903517/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

79. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903517/A resided with Minimatic Implant Technology, Inc.

80. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903517. The database further states that the 510(k) was received by FDA on August 3, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K903516/A (PART No. 1121)

81. The 510(k) which resulted in 510(k) clearance K903516/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

82. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903516/A resided with Minimatic Implant Technology, Inc.

83. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903516. The database further states that the 510(k) was received by FDA on August 3, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K903518/A (PART No. 1122)

84. The 510(k) which resulted in 510(k) clearance K903518/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

85. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K903518/A resided with Minimatic Implant Technology, Inc.

86. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K903518. The database further states that the 510(k) was received by FDA on August 3, 1990, and was cleared on November 20, 1990.

510(k) CLEARANCE No. K904703/A (PART No. 1201)

87. The FDA's responsive correspondence indicates that the 510(k) which resulted in 510(k) clearance K904703/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

88. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904703/A resided with Minimatic Implant Technology, Inc.

89. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904703. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 15, 1991.

510(k) CLEARANCE No. K904704/A (PART No. 1203)

90. The 510(k) which resulted in 510(k) clearance K904704/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

91. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904704/A resided with Minimatic Implant Technology, Inc.

92. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904704. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 21, 1991.

510(k) CLEARANCE No. K904705/A (PART No. 1206)

93. The 510(k) which resulted in 510(k) clearance K904705/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

94. Leon Shaw's letter of January 4, 1991, referencing 510(k) number K904705, identifies Dr. Jack Krauser as a "professional consultant" and notes that a letter submitted by Dr. Krauser was "with our authority". Mr. Shaw's letter is consistent with industry practice and indicates that Minimatic Implant Technology, Inc. owned the subject 510(k) and the resulting clearance, K904705/A.

95. Dr. Jack Krauser's letter of December 27, 1990, referencing 510(k) number K904705, identifies Dr. Krauser as a "Consultant to Minimatic Incorporated" and carbon copies Leon Shaw in his capacity as President of Minimatic Inc. This letter is consistent with industry practice and indicates that Minimatic Inc. owned the subject 510(k) and the resulting clearance, K904075/A.

96. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904705/A resided with Minimatic Implant Technology, Inc.

97. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904705. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on April 12, 1991.

510(k) CLEARANCE No. K904706/A (PART No. 1207)

98. The 510(k) which resulted in 510(k) clearance K904706/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

99. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904706/A resided with Minimatic Implant Technology, Inc.

100. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904706. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 21, 1991.

510(k) CLEARANCE No. K904707/A (PART No. 1208)

101. The 510(k) which resulted in 510(k) clearance K904707/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

102. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904707/A resided with Minimatic Implant Technology, Inc.

103. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904707. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on April 29, 1991.

510(k) CLEARANCE No. K904708/A (PART No. 1211)

104. The 510(k) which resulted in 510(k) clearance K904708/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

105. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904708/A resided with Minimatic Implant Technology, Inc.

106. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904708. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 21, 1991.

510(k) CLEARANCE No. K904709/A (PART No. 1213)

107. The 510(k) which resulted in 510(k) clearance K904709/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

108. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904709/A resided with Minimatic Implant Technology, Inc.

109. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904709. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 21, 1991.

510(k) CLEARANCE No. K904710/A (PART No. 1219)

110. The 510(k) which resulted in 510(k) clearance K904710/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

111. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904710/A resided with Minimatic Implant Technology, Inc.

112. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904710. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 29, 1991.

510(k) CLEARANCE No. K904711 (PART No. 1220)

113. The 510(k) which resulted in 510(k) clearance K904711 was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

114. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904711 resided with Minimatic Implant Technology, Inc.

115. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904711. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on January 14, 1991.

510(k) CLEARANCE No. K904712/A (PART No. 1221)

116. The 510(k) which resulted in 510(k) clearance K904712/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

117. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K904712/A resided with Minimatic Implant Technology, Inc.

118. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K904712. The database further states that the 510(k) was received by FDA on October 16, 1990, and was cleared on March 29, 1991.

510(k) CLEARANCE No. K905039/A (PART No. 1306)

119. The FDA's responsive correspondence indicates that the 510(k) which resulted in 510(k) clearance K905039/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

120. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K905039/A resided with Minimatic Implant Technology, Inc.

121. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K905039. The database further states that the 510(k) was received by FDA on November 6, 1990, and was cleared on April 29, 1991.

510(k) CLEARANCE No. K911112 (PART No. 1400 SERIES)

122. The 510(k) which resulted in 510(k) clearance K911112 was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

123. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K911112 resided with Minimatic Implant Technology, Inc.

124. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K911112. The database further states that the 510(k) was received by FDA on February 13, 1991, and was cleared on June 10, 1991.

510(k) CLEARANCE No. K902931/A (PART No. PD-12)

125. The 510(k) which resulted in 510(k) clearance K902931/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

126. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K902931/A resided with Minimatic Implant Technology, Inc.

127. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K902931. The database further states that the 510(k) was received by FDA on July 5, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K902929 (PART No. SVD 2,3,4)

128. The 510(k) which resulted in 510(k) clearance K902929/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

129. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K902929/A resided with Minimatic Implant Technology, Inc.

130. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K902929. The database further states that the 510(k) was received by FDA on July 3, 1990, and was cleared on November 13, 1990.

510(k) CLEARANCE No. K902930/A (PART No. SVD-3S)

131. The 510(k) which resulted in 510(k) clearance K902930/A was submitted by Leon Shaw on behalf of Minimatic Implant Technology, Inc.

132. Based on the FDA's correspondence with Leon Shaw and Minimatic Implant Technology, Inc., I conclude that the FDA understood that ownership of 510(k) clearance K902930/A resided with Minimatic Implant Technology, Inc.

133. Consistent with my conclusion, the FDA's 510(k) database identifies "Minimatic Implant Technology" as the applicant for 510(k) No. K902930. The database further states that the 510(k) was received by FDA on July 5, 1990, and was cleared on November 20, 1990.

510(k) CLEARANCE No. K911776

134. I have reviewed the 510(k) database entry for 510(k) No. K911776, titled "DPI-1106 Implant, Modification". The database states that the 510(k) was received by FDA on April 1, 1991, and cleared on January 15, 1992. Based on the 510(k) database entry, I conclude that FDA understood that ownership of 510(k) No. K911776 resided with Minimatic Implant Technology.

510(k) CLEARANCE No. K952905

135. I have reviewed the 510(k) database entry for 510(k) No. K952905, titled "Minimatic Various Implant Systems". The database states that the 510(k) was received by FDA on June 22, 1995, and cleared on April 16, 1997. Based on the 510(k) database entry, I conclude that FDA understood that ownership of 510(k) No. K952905 resided with Minimatic, Inc.

V. ORIGINAL OWNERSHIP OF BIOHORIZONS AND BIO-LOK 510(k)S

136. Dr. Krauser's asserted claims of ownership regarding 510(k)s submitted by Bio Horizons Implant Systems, Inc. or Bio-Lok International, Inc., including the resulting clearances, are less than clear. See Second Amended Compl. ¶ 24. As such, I have been asked to provide an opinion regarding the ownership of all 510(k)s, including the associated clearances issued to those two companies.

137. In order to identify relevant 510(k)s, I searched the FDA's 510(k) Premarket Notification Database. A March 13, 2012, search for "Applicant Name" "BioHorizons" yielded 29 results, and a search for "Applicant Name" "Bio-Lok" yielded three results.

138. Each of the BioHorizons and Bio-Lok 510(k)s that I reviewed was received by FDA well-after the timeframe of Dr. Krauser's relationship with Minimatic, which I am informed ended in 1993. Indeed, the earliest was received by FDA on January 2, 1996. And only three of the 510(k)s that I reviewed—BioHorizons 510(k) Nos. K960026, K963951, and K964330—were submitted prior to the October 1996 Settlement. Notably, however, none of those 510(k)s were identified in the October 1996 Settlement Agreement or Dr. Krauser's July 12, 1996, Amended Proof of Claim.

139. In all cases, as I will review below, BioHorizons's 510(k)s indicate that BioHorizons both submitted and owned the 510(k)s. While the 510(k)s identify predicate devices for purposes of showing substantial equivalence, as is required in the 510(k) process, this

has no bearing on ownership. Regardless of who owns the predicate devices (and, in most cases, the predicate devices belonged to BioHorizons), ownership of the BioHorizons 510(k)s would remain with BioHorizons. Thus, even if Dr. Krauser owned the Minimatic 510(k)s as he claims (and I do not believe he does), that would not give him ownership of BioHorizons's 510(k)s.

140. In short, BioHorizons's 510(k) clearances are separate and distinct regulatory clearances from those issued to Minimatic. Thus, even if Dr. Krauser did own the Minimatic 510(k)s, that would have no impact on the ownership of BioHorizons's 510(k)s, and BioHorizons (or its transferee) can lawfully market devices under its own 510(k)s without regard to who owns the Minimatic 510(k)s.

141. In all cases, as I will review below, Bio-Lok's 510(k)s indicate that Bio-Lok both submitted and owned the 510(k)s. While the 510(k)s identify predicate devices for purposes of showing substantial equivalence, as is required in the 510(k) process, this has no bearing on ownership. Regardless of who owns the predicate devices, ownership of the Bio-Lok 510(k)s would remain with Bio-Lok. Thus, even if Dr. Krauser owned the Minimatic 510(k)s as he claims (and I do not believe he does), that would not give him ownership of Bio-Lok's 510(k)s.

142. In short, Bio-Lok's 510(k) clearances are separate and distinct regulatory clearances from those issued to Minimatic. Thus, even if Dr. Krauser did own the Minimatic 510(k)s, that would have no impact on the ownership of Bio-Lok's 510(k)s, and Bio-Lok (or its transferee) can lawfully market products under its own 510(k)s without regard to who owns the Minimatic 510(k)s.

A. ORIGINAL OWNERSHIP OF BIOHORIZONS'S 510(k)S

510(k) No. K103291

143. I have reviewed the 510(k) database entry and summary for 510(k) No. K103291, titled "BioHorizons Laser-Lok Abutments for Nobel Biocare". The database states that the

510(k) was received by FDA on November 8, 2010, and cleared on November 4, 2011. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K103291 resided with BioHorizons Implant Systems, Inc.

144. The 510(k) summary for K103291 identifies 13 predicate devices. Only one of the 13 predicate devices is identified as the subject of a BioHorizons 510(k) (K100985). None of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K103691

145. I have reviewed the 510(k) database entry and summary for 510(k) No. K103691, titled "BioHorizons Abutments for Zimmer". The database states that the 510(k) was received by FDA on December 17, 2010, and cleared on November 3, 2011. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K103691 resided with BioHorizons Implant Systems, Inc.

146. The 510(k) summary for K103691 identifies 10 predicate devices, only 3 of which are identified as the subject of BioHorizons 510(k)s (K100985, K073268, K071638). None of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K100985

147. I have reviewed the 510(k) database entry and summary for 510(k) No. K100985, titled "BioHorizons Simple Solutions with Laser-Lok". The database states that the 510(k) was received by FDA on April 9, 2010, and cleared on September 9, 2010. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K100985 resided with BioHorizons Implant Systems, Inc.

148. The 510(k) summary for K100985 identifies 5 predicate devices. Four of the predicate devices are identified as the subject of BioHorizons 510(k)s (K073282, K073268, K071638, K093321), and one is identified as the subject of a Zimmer Dental 510(k). None of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K093321

149. I have reviewed the 510(k) database entry and summary for 510(k) No. K093321, titled "BioHorizons Laser-Lok 3.0 Implant System". The database states that the 510(k) was received by FDA on October 23, 2009, and cleared on April 2, 2010. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K093321 resided with BioHorizons Implant Systems, Inc.

150. The 510(k) summary for K093321 identifies 4 predicate devices. Three of the predicate devices are identified as the subject of BioHorizons 510(k)s (K073268, K052419, K071638), and one is identified as the subject of an Astra Tech 510(k). None of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K081818

151. I have reviewed the 510(k) database entry and summary for 510(k) No. K081818, titled "BioHorizons Micro-Lok Implant System". The database states that the 510(k) was received by FDA on June 27, 2008, and cleared on November 13, 2008. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K081818 resided with BioHorizons Implant Systems, Inc.

152. The 510(k) summary for K081818 identifies the Minimatic (BioLok International) Various Implant Systems, documented under 510(k) No. K952905 as the predicate

device. I am informed, however, that the BioHorizons Micro-Lok Implant System is no longer actively marketed in the United States.

510(k) No. K073282

153. I have reviewed the 510(k) database entry and summary for 510(k) No. K073282, titled "BioHorizons Single-stage Implant System". The database states that the 510(k) was received by FDA on November 21, 2007, and cleared on February 15, 2008. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K073282 resided with BioHorizons Implant Systems, Inc.

154. The 510(k) summary for K073282 identifies the BioHorizons Single-Stage Implant System (K053152) and the BioHorizons Tapered Internal Implant System (K071638) as predicate devices. Neither predicate device is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K073268

155. I have reviewed the 510(k) database entry and summary for 510(k) No. K073268, titled "BioHorizons Internal Implant System". The database states that the 510(k) was received by FDA on November 20, 2007, and cleared on February 8, 2008. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K073268 resided with BioHorizons Implant Systems, Inc.

156. The 510(k) summary for K073268 identifies two predicate devices, both of which are identified as the subject of BioHorizons 510(k)s (K042429, K071638). Neither predicate device is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K071638

157. I have reviewed the 510(k) database entry and summary for 510(k) No. K071638, titled "BioHorizons Tapered Internal Implant System". The database states that the 510(k) was

received by FDA on June 15, 2007, and cleared on October 10, 2007. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K071638 resided with BioHorizons Implant Systems, Inc.

158. The 510(k) summary for K071368 does not identify the predicate devices on which the 510(k) submission relies. But the 510(k) itself identifies two BioHorizons devices as predicates, The Prodigy Implant System (K042429) and The Maestro System 3.0 (K032351), and one Bio-Lok device, Silhouette and Silhouette IC Endosseous Implant (K032454, K041136). None of the predicate devices are identified as manufactured, distributed, or marketed by Minimatic.

510(k) No. K061567

159. I have reviewed the 510(k) database entry and summary for 510(k) No. K061567, titled "BioHorizons Ceramic Abutment". The database states that the 510(k) was received by FDA on June 6, 2006, and cleared on November 22, 2006. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K061567 resided with BioHorizons Implant Systems, Inc.

160. The 510(k) summary for K061567 identifies two predicate devices. One predicate device is identified as the subject of a BioHorizons 510(k) (K042429), and one is identified as the subject of an Astra Tech 510(k). Neither predicate device is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, the BioHorizons predicate device 510(k) identified in K061567 does not identify a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K053099

161. I have reviewed the 510(k) database entry and summary for 510(k) No. K053099, titled "BioHorizons Plastic Temporary Abutments". The database states that the 510(k) was

received by FDA on November 3, 2005, and cleared on February 14, 2006. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K053099 resided with BioHorizons Implant Systems, Inc.

162. The 510(k) summary for K053099 identifies two predicate devices. One predicate device is identified as the subject of a Dentsply International 510(k), and one is identified as the subject of a Straumann Manufacturing 510(k). Neither predicate device is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K053152

163. I have reviewed the 510(k) database entry and summary for 510(k) No. K053152, titled "BioHorizons Single-Stage Implant". The database states that the 510(k) was received by FDA on November 10, 2005, and cleared on December 2, 2005. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K053152 resided with BioHorizons Implant Systems, Inc.

164. The 510(k) summary for K053152 identifies the BioHorizons The Maestro System (K020645) and the BioHorizons The Prodigy System (K042429) as predicate devices. Neither predicate device is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, neither of the BioHorizons predicate device 510(k)s identified in K053152 identifies a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K052419

165. I have reviewed the 510(k) database entry and summary for 510(k) No. K052419, titled "Maximus 3.0 and OS Implants". The database states that the 510(k) was received by FDA on September 2, 2005, and cleared on September 20, 2005. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K052419 resided with BioHorizons Implant Systems, Inc.

166. The 510(k) summary for K052419 identifies three predicate devices, each of which is identified as the subject of a BioHorizons 510(k). The BioHorizons Dental Implant System is identified as the subject of 510(k) No. K960026; The BioHorizons Maestro System is identified as the subject of 510(k) No. K032351, and the BioHorizons Maximus OS (Overdenture System) Implant is identified as the subject of 510(k) No. K041938. None of the predicate devices was identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none of the BioHorizons predicate device 510(k)s identified in K052419 identifies a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K042429

167. I have reviewed the 510(k) database entry and summary for 510(k) No. K042429, titled "The Prodigy System Dental Implants". The database states that the 510(k) was received by FDA on September 8, 2004, and cleared on September 16, 2004. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K042429 resided with BioHorizons Implant Systems, Inc.

168. The 510(k) summary for K042429 identifies a single predicate device. The predicate device is identified as the subject of multiple BioHorizons 510(k)s (K960026, K010458, K020133, K030463). The predicate device is not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none of the BioHorizons predicate device 510(k)s identified in K042429 identifies a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K041938

169. I have reviewed the 510(k) database entry and summary for 510(k) No. K041938, titled "Maximus OS (Overdenture System)". The database states that the 510(k) was received by FDA on July 19, 2004, and cleared on July 22, 2004. Based on the 510(k) database entry and

summary, I conclude that FDA understood that ownership of 510(k) No. K041938 resided with BioHorizons Implant Systems, Inc.

170. The 510(k) summary for K041938 identifies two predicate devices. Both predicate devices are identified as the subject of BioHorizons 510(k)s (K032351, K023067). However, based on a review of the FDA's database, K023067 is an Imtec Corp. 510(k) for an endosseous dental implant. After reviewing relevant portions of the 510(k) for K041938, I determined that 510(k) No. K023067 was erroneously listed in the 510(k) summary, and that this 510(k) identifies 510(k) Nos. K032351 and K990277 as the predicate devices. Neither predicate device is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, the BioHorizons predicate device 510(k)s identified in K041938 do not identify a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K032351

171. I have reviewed the 510(k) database entry and summary for 510(k) No. K032351, titled "The Maestro System 3.0mm Diameter Implant". The database states that the 510(k) was received by FDA on July 31, 2003, and cleared on October 21, 2003. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K032351 resided with BioHorizons Implant Systems, Inc.

172. The 510(k) summary for K032351 identifies three predicate devices. One predicate device is identified as the subject of multiple BioHorizons 510(k)s (K960026, K964330, K972313, K010458, K020133, K020645, K022795, K030463), one predicate device is identified as the subject of an Altiva Corp. 510(k), and one predicate device is identified as the subject of multiple Imtec Corp. 510(k)s. None of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none

of the BioHorizons predicate device 510(k)s identified in K032351 identifies a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K030463

173. I have reviewed the 510(k) database entry and summary for 510(k) No. K030463, titled "Modification to the Maestro System". The database states that the 510(k) was received by FDA on February 12, 2003, and cleared on February 26, 2003. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K030463 resided with BioHorizons Implant Systems, Inc.

174. The 510(k) summary for K030463 identifies a single predicate that is the subject of multiple BioHorizons 510(k)s (K960026, K964330, K972313, K010458, K020133, K020645, K022795). The predicate device is not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none of the BioHorizons predicate device 510(k)s identified in K030463 identifies a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K022795

175. I have reviewed the 510(k) database entry and summary for 510(k) No. K022795, titled "Modification to the Maestro System". The database states that the 510(k) was received by FDA on August 23, 2002, and cleared on August 30, 2002. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K022795 resided with BioHorizons Implant Systems, Inc.

176. The 510(k) summary for K022795 identifies two predicate devices. One predicate device is identified as the subject of multiple BioHorizons 510(k)s (K010458, K960026, K964330, K972313, K010458, K020133, K020645), and one predicate device is identified as the subject of a 3i 510(k). Neither of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none

of the BioHorizons predicate device 510(k)s identified in K022795 identifies a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K022790

177. I have reviewed the 510(k) database entry and summary for 510(k) No. K022790, titled "The Autotac System Titanium Tack". The database states that the 510(k) was received by FDA on August 22, 2002, and cleared on August 28, 2002. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K022790 resided with BioHorizons Implant Systems, Inc.

178. The 510(k) summary identifies three predicate devices. One of the predicate devices is identified as the subject of multiple BioHorizons 510(k)s (K993493, K011675); one of the predicate devices is identified as the subject of an Interpore Systems, Inc. 510(k), and one of the predicate devices is identified as the subject of an Imtec 510(k). None of the predicate devices is identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, neither of the BioHorizons predicate device 510(k)s identified in K022790 identifies Minimatic or Bio-Lok devices as predicate devices.

510(k) No. K020645

179. I have reviewed the 510(k) database entry and summary for 510(k) No. K020645, titled "Modification to the Maestro System". The database states that the 510(k) was received by FDA on February 28, 2002, and cleared on March 15, 2002. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K020645 resided with BioHorizons Implant Systems, Inc.

180. The 510(k) summary for K020645 identifies a single predicate device that is the subject of multiple BioHorizons 510(k)s (K010458, K960026, K964330, K972313, K010458, K020133). After reviewing relevant portions of the 510(k) for K020645, I conclude that

K010458 was erroneously listed twice. The 510(k) for K020645 identifies BioHorizons 510(k)s K010458, K960026, K964330, K972313, K010458, K020133 as covering the predicate device. The predicate device is not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none of the predicate device 510(k)s identified in K011675 identify Minimatic or Bio-Lok devices as predicate devices.

510(k) No. K020133

181. I have reviewed the 510(k) database entry and summary for 510(k) No. K020133, titled "Modification to the Maestro System". The database states that the 510(k) was received by FDA on January 15, 2002, and cleared on January 25, 2002. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K020133 resided with BioHorizons Implant Systems, Inc.

182. The 510(k) summary for K020133 identifies a single predicate device that is the subject of multiple BioHorizons 510(k)s (K010458, K972313, K960026, K964330). The predicate device is not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, none of the predicate device 510(k)s identified in K020133 identify Minimatic or Bio-Lok devices as predicate devices.

510(k) No. K011675

183. I have reviewed the 510(k) database entry and summary for 510(k) No. K011675, titled "The Autotac System". The database states that the 510(k) was received by FDA on May 30, 2001, and cleared on June 22, 2001. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K011675 resided with BioHorizons Implant Systems, Inc.

184. The 510(k) summary for K011675 identifies a single predicate device that is the subject of a single BioHorizons 510(k) (K993493). The predicate device is not identified as

manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, the predicate device 510(k) identified in K011675 does not identify Minimatic or Bio-Lok devices as predicate devices.

510(k) No. K010458

185. I have reviewed the 510(k) database entry and summary for 510(k) No. K010458, titled "The Maestro System". The database states that the 510(k) was received by FDA on February 16, 2001, and cleared on May 10, 2001. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K010458 resided with BioHorizons Implant Systems, Inc.

186. The 510(k) summary for K010458 identifies a single predicate device that is identified as the subject of three BioHorizons 510(k)s (K96433, K964330, and K972313). Based on a database search for the identified 510(k)s, I conclude that K96433 was listed in error. I confirmed that conclusion by reviewing relevant portions of the 510(k) for K010458, which identifies K960026, K964330, and K972313 as the relevant 510(k)s. The predicate device is not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, the BioHorizons predicate device 510(k)s identified in K010458 do not identify a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K993493

187. I have reviewed the 510(k) database entry and summary for 510(k) No. K993493, titled "The Autotac System". The database states that the 510(k) was received by FDA on October 15, 1999, and cleared on January 7, 2000. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K993493 resided with BioHorizons Implant Systems, Inc.

188. The 510(k) summary for K993493 identifies the Biovision GmbH LEADfix Bioresorbable Membrane Pin System and the 3i BIO TACK as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K990277

189. I have reviewed the 510(k) database entry and summary for 510(k) No. K990277, titled "O-Ring Abutment". The database states that the 510(k) was received by FDA on January 28, 1999, and cleared on April 9, 1999. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K990277 resided with BioHorizons Implant Systems, Inc.

190. The 510(k) summary for K990277 identifies the Lifecore Biomedical, SteriOss, and Implant Innovations O-Ring Abutment Systems as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K980374

191. I have reviewed the 510(k) database entry and summary for 510(k) No. K980374, titled "Implant Site Dilators". The database states that the 510(k) was received by FDA on January 30, 1998, and cleared on March 4, 1998. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K980374 resided with BioHorizons Implant Systems, Inc.

192. The 510(k) summary for K980374 does not identify the predicate devices on which the 510(k) relies. After a telephone interview with BioHorizons employee Winston Greer, I am informed that K980374 relies on a single predicate device, the Steri-Oss "Osteo Compaction Kit", and that the predicate device is not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K972313

193. I have reviewed the 510(k) database entry and summary for 510(k) No. K972313, titled "The Maestro System". The database states that the 510(k) was received by FDA on June 20, 1997, and cleared on September 16, 1997. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K972313 resided with BioHorizons Implant Systems, Inc.

194. The 510(k) summary for K972313 identifies the BioHorizons Dental Implant System (K964330) and the Steri-Oss Hex-Lock Threaded Implants as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, the BioHorizons predicate device 510(k) identified in K972313 does not identify a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K964330

195. I have reviewed the 510(k) database entry and summary for 510(k) No. K964330, titled "BioHorizons Dental Implant System". The database states that the 510(k) was received by FDA on October 31, 1996, and cleared on January 17, 1997. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K964330 resided with BioHorizons Implant Systems, Inc.

196. The 510(k) summary for K964330 identifies the BioHorizons Dental Implant System (K960026) and the Steri-Oss Hex-Lock (HL) Threaded Titanium Implants as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok. And, as detailed below, the BioHorizons predicate device 510(k) identified in K964330 does not identify a Minimatic or Bio-Lok device as a predicate device.

510(k) No. K963951

197. I have reviewed the 510(k) database entry and summary for 510(k) No. K963951, titled "AS 123 Prosthetic Instrumentation System". The database states that the 510(k) was received by FDA on October 2, 1996, and cleared on December 31, 1996. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K963951 resided with BioHorizons Implant Systems, Inc.

198. The 510(k) summary for K963951 identifies the Steri-Oss Prosthetic Instrumentation and the Implant Innovations, Inc. Drivers and Placement Instruments as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K960026

199. I have reviewed the 510(k) database entry and summary for 510(k) No. K960026, titled "BioHorizons Dental Implant System". The database states that the 510(k) was received by FDA on January 2, 1996, and cleared on March 28, 1996. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K960026 resided with BioHorizons Implant Systems, Inc.

200. The 510(k) summary for K960026 identifies the Steri-Oss Hex-Lock (HL) Threaded Titanium Implants and the Branemark System Implants as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

B. OWNERSHIP OF BIO-LOK'S 510(k)s

510(k) No. K060285

201. I have reviewed the 510(k) database entry and summary for 510(k) No. K060285, titled "BoneGen - TR". The database states that the 510(k) was received by FDA on February 6,

2006, and cleared on March 16, 2006. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K060285 resided with Bio-Lok International, Inc.

202. The 510(k) summary for K060285 identifies Orthogen Corp.'s SurgiPlaster, Lifecore Biomedical Inc.'s CalMatrix Calcium Sulfate Bone Graft Binder, and OsteoBiologics, Inc.'s Plygraft Bone Graft Substitute, and Atrix Laboratories, Inc.'s Atrisorb Bioabsorbable GTR Barrier as predicate devices. None of the predicate devices are identified as manufactured, distributed, or marketed by Minimatic or Bio-Lok.

510(k) No. K041136

203. I have reviewed the 510(k) database entry and summary for 510(k) No. K041136, titled "Modification to Silhouette IC or Silhouette; Laser-Lok Surface Treatment -Optional Surface Modification to Implants". The 510(k) database indicates that the 510(k) was received by FDA on April 30, 2004, and cleared on October 22, 2004. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K041136 resided with Bio-Lok International, Inc.

204. The 510(k) summary for K041136 identifies the Bio-Lok Silhouette and Silhouette IC dental implants (K032454) as predicate devices. The predicate devices are not identified as manufactured, distributed, or marketed by Minimatic.

510(k) No. K032454

205. I have reviewed the 510(k) database entry and summary for 510(k) No. K032454, titled "Silhouette(TM) IC or Silhouette(TM) & Laser-Lok (TM)". The 510(k) database indicates that the 510(k) was received by the FDA on August 16, 2003, and cleared on March 4, 2004. Based on the 510(k) database entry and summary, I conclude that FDA understood that ownership of 510(k) No. K032454 resided with Bio-Lok International., Inc.

206. The 510(k) summary for K032454 identifies Micro-Lok implants, Astra Tech Fixture ST, Osseotite NT from 3I, and Frialit-2 by Dentsply Friadent Ceramed implants as predicate devices.

I declare under penalty of perjury that the foregoing is true and correct.

May 8, 2012

Heather Rosecrans