Almer v. Peanut Corporation of America Doc. 501

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

In re: Guidant Defibrillators Products Liability Litigation	**MDL Case No. 1708 (DWF/AJB)**
Relates to ALL ACTIONS	

AMENDED AFFIDAVIT OF BRIAN NOVAK

I, Brian Novak, declare as follows:

1. I am the Manager of Regulatory Affairs at Cardiac Pacemakers, Inc. ("CPI"), 4100 North Hamline Avenue, St. Paul, Minnesota 55112. If called and sworn as a witness, I will competently testify that the matters stated in this declaration are true and correct, based upon my personal knowledge of such matters. All statements contained herein are based upon my own personal knowledge of these facts, or upon my personal review of records kept and maintained by CPI in the regular course of its business.

2. I have served as Manager of Regulatory Affairs at CPI since September 1, 2001. My prior experience at CPI has been as Senior Engineer, Supervisor of Field Performance Monitoring, Regulatory Affairs Associate, Lead Regulatory Affairs Associate, and Manager of Corporate Audit. My prior regulatory experience includes preparing and submitting CPI's regulatory submissions (Class III Pre-Market Approval Applications, Product Development Protocols, § 510(k) Applications, and Investigational Device Exemption Applications) from September 1, 1997 through October 31, 2000. My professional education includes a Bachelor of Science degree in Electrical Engineering

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from the University of Wisconsin, Madison. As a result of my experience and training, I am thoroughly familiar with the Food and Drug Administration's regulations and requirements governing medical device design, testing, labeling, manufacturing, adverse event reporting and related issues.

3. In my capacity as Manager of Regulatory Affairs for CPI, I have responsibility for various matters involving the United States Food and Drug Administration ("FDA"). My responsibilities include regulatory submissions to the FDA for CPI's cardiac defibrillation products, such as automatic implantable cardioverter defibrillators ("AICDs") and leads. My responsibilities also include working with CPI personnel to ensure that CPI's pacing system products comply with FDA requirements, and submitting proper documentation to the FDA to maintain compliance with FDA regulations.

4. I am the keeper of the records for CPI as they relate to regulatory submissions. I am familiar with documents and materials sent by CPI to the FDA, as well as documents sent by the FDA to CPI.

5. The records of CPI, including the exhibits attached to this Affidavit, are documents made and/or received by CPI at or near the time of the acts and events described or otherwise referenced in them. These documents are made and/or kept by CPI in the ordinary course of its regularly conducted business activities.

6. AICDs are classified by the FDA as "Class III" medical devices. Class III medical devices are subject to the strictest FDA controls. 21 C.F.R. § 860.3(c)(3).

Except in certain circumstances, none of which are present in this case, a Class III medical device may not be placed into commerce unless the manufacturer has provided the FDA with reasonable assurance that the device – as designed, manufactured and labeled – is safe and effective for its intended use. The regulatory process through which a manufacturer seeks FDA approval is known as the Pre-Market Approval ("PMA") process.

7. The CPI AICD at issue in this case is the VENTAK PRIZM 2 DR, Model 1861 ("PRIZM 2"). The PRIZM 2 is a Class III medical device. To obtain approval for the PRIZM 2, CPI submitted to the FDA a supplemental PMA application. The supplemental PMA application for the PRIZM 2 relied, in part, upon information previously provided to the FDA in PMA submissions for predecessor devices, including: (1) the VENTAK AV AICD System, PMA No. P960040 (submitted August 19, 1996, approved on July 18, 1997) and (2) the VENTAK PRIZM VR/DR, PMA No. P960040/S12 (submitted August 21, 1999, approved January 21, 2000). Because the FDA considers the entire family of predecessor PMA applications when it evaluates a supplemental PMA application, a review of these predecessor PMA applications is relevant.

The VENTAK AV AICD System

8. CPI submitted to the FDA a PMA application for the VENTAK AV on August 19, 1996.

9. This PMA application sought FDA approval for the sale, distribution, and use of the VENTAK AV as a prescription medical device, pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Medical Device Amendments of 1976 ("MDA"). As set forth in its PMA, the VENTAK AV monitors and regulates a patient's heart rate by providing therapy for ventricular arrhythmias, and it provides dual-chamber bradycardia pacing if required. The implantable portion of the VENTAK AV consists of a pulse generator and leads for sensing cardiac rate and for delivering pacing pulses and cardioversion/defibrillation shocks. An atrial lead port is available to allow sensing and bradycardia pacing in the atrium.

10. The PMA application for the VENTAK AV consists of over 4,500 pages of data in accordance with FDA regulations, including detailed, device-specific information concerning the design, manufacturing methods and processes, quality control procedures, indications and uses, contraindications, potential adverse events and effects, warnings and precautions, labeling, marketing, and distribution of the device. The PMA application also includes detailed results of various studies – bench testing, functionality testing, simulated use testing, safety testing/analysis, biocompatibility studies, animal studies, and clinical studies. The VENTAK AV PMA application also incorporates by reference data previously submitted to the FDA in connection with the approved PMA application for CPI's "PRx" family of AICDs, PMA No. P910077.

11. Prior to approving the VENTAK AV, the FDA made numerous inquiries to CPI about the PMA application, requested clarification of questions, and required the submission of additional material.

12. On July 18, 1997, the FDA, through its Office of Device Evaluation, Center for Devices and Radiological Health, approved CPI's PMA application for the VENTAK AV and authorized CPI to begin commercial distribution of the device upon receipt of the FDA notification. *See* July 18, 1997 Approval Letter from Susan Alpert, Ph.D., M.D., Director, Office of Device Evaluation, Center for Devices and Radiological Health, FDA **(Exhibit A)**.

13. The FDA's approval letter of July 18, 1997 constitutes a finding that the VENTAK AV is safe and effective.

14. At all times since PMA approval, CPI has maintained approval of the VENTAK AV as a Class III medical device in compliance with federal regulations and with continuing FDA supervision.

15. Thus, the first device in the VENTAK PRIZM/AV family has maintained FDA approval since 1997.

The VENTAK PRIZM VR/DR

16. CPI submitted to the FDA a Supplemental PMA application for the VENTAK PRIZM VR/DR devices on August 21, 1999.

17. The supplemental PMA application sought FDA approval for the sale, distribution, and use of the VENTAK PRIZM VR/DR. The VENTAK PRIZM VR/DR

devices were built upon technology from predecessor devices – the VENTAK AV and the VENTAK VR. The VENTAK PRIZM VR/DR devices were downsized versions of the VENTAK AV and VENTAK VR and incorporated CPI's latest brady enhancements. Their oval shape and decreased weight made the VENTAK PRIZM VR/DR devices smaller and more physiologically shaped.

18. The VENTAK PRIZM VR/DR supplemental PMA application, which consists of over 2,100 pages of data, provided the FDA with scientifically supported justification for the aforementioned changes, including detailed, device-specific information concerning the design, manufacturing methods and processes, quality control procedures, studies, indications and uses, contraindications, potential adverse events and effects, warnings and precautions, labeling, marketing, and distribution of the device.

19. Prior to approving the VENTAK PRIZM VR/DR, the FDA made numerous inquiries to CPI about the supplemental PMA submission, requested clarification of questions, and required the submission of additional material.

20. On January 21, 2000, the FDA, through its Office of Device Evaluation, Center for Devices and Radiological Health, approved CPI's supplemental PMA application for the VENTAK PRIZM VR/DR and authorized CPI to begin commercial distribution of the device upon receipt of the FDA notification. *See* January 21, 2000 Approval Letter from Nancy C. Brogdon for Celia M. Witten, Ph.D., M.D., Acting Director, Division of Cardiovascular, Respiratory, and Neurological Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA (**Exhibit B**).

21. The FDA's approval letter of January 21, 2000 constitutes a finding that the VENTAK PRIZM VR/DR is safe and effective.

22. At all times since PMA approval, CPI has maintained approval of the VENTAK PRIZM VR/DR as a Class III medical device in compliance with federal regulations and with continuing FDA supervision.

The PRIZM 2

23. CPI submitted to the FDA a supplemental PMA application for the PRIZM 2 on June 7, 2000.

24. This supplemental PMA application sought FDA approval for the sale, distribution, and use of the PRIZM 2 as a prescription medical device. As noted above, the supplemental PMA application for the PRIZM 2 relied, in part, upon information previously provided to the FDA in PMA submissions for the VENTAK AV AICD System and the VENTAK PRIZM VR/DR.

25. In its supplemental PMA application for the PRIZM 2, CPI submitted over 1,800 pages of data in accordance with FDA regulations, including detailed, device-specific information concerning the design, manufacturing methods and processes, quality control procedures, studies, indications and uses, contraindications, potential adverse events and effects, warnings and precautions, labeling, marketing, and distribution of the device.

26. Specifically, the Supplemental PMA application sought FDA approval for the expansion of the VENTAK PRIZM/AV family to include two downsized models –

the VENTAK PRIZM 2 DR, Model 1860 and the VENTAK PRIZM 2 DR, Model 1861 (the device at issue here). The submission described in detail the mechanical and software changes necessary to achieve smaller device size, to improve ease of use, and to enhance the overall function of the PRIZM 2 in comparison to predecessor devices. The supplemental PMA application for the PRIZM 2 also sought FDA approval for revised and reformatted product labeling, including updates to the Physician's Technical Manual, the System Guide, and the Patient Handbook. With regard to the PRIZM 2, there were no modifications to the fundamental tachyarrhythmia and bradycardia therapies from previous VENTAK PRIZM family models, and the warnings and indications for use are identical to those for the VENTAK PRIZM DR/VR.

27. The Supplemental PMA application for the PRIZM 2 provided the FDA with scientifically supported justification for the foregoing changes and reinforced the safety and effectiveness of the device family by including extensive testing data, including but not limited to information concerning: (1) battery longevity; (2) electromagnetic interference; (3) electronic design verification; (4) mechanical design verification; (5) software design verification; (6) system feature testing; (7) arrhythmia scenario analysis; (8) simulated use testing; (9) system hazard analysis; (10) failure modes and effects criticality analysis; (11) reliability predictions; (12) component qualification; (13) animal studies; and (14) biocompatibility studies.

28. Prior to approving the PRIZM 2, the FDA made numerous inquiries to CPI about the supplemental PMA submission, requested clarification of questions, and required the submission of additional material.

29. On August 4, 2000, the FDA, through its Office of Device Evaluation, Center for Devices and Radiological Health, approved CPI's supplemental PMA application for the PRIZM 2 and authorized CPI to begin commercial distribution of the device upon receipt of the FDA notification (PMA No. P960040/S15). *See* August 4, 2000 Approval Letter from James E. Dillard III, Director, Division of Cardiovascular and Respiratory Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA (**Exhibit C**).

30. The FDA's approval letter of August 4, 2000 constitutes a finding that the PRIZM 2 is safe and effective.

31. Further, as part of the PMA-approval process, the FDA reviewed and approved detailed instructions, warnings, and product labeling for the PRIZM 2 intended for both physicians and patients. Theses materials included express warnings regarding the possible side effects, complications, and adverse events associated with the use of a cardiac defibrillation system. Specifically, these materials warn both patients and physicians that the PRIZM 2 might be unable to defibrillate or pace.

32. Approval of the supplemental PMA application for the PRIZM 2 was subject to additional "Conditions of Approval," which prohibit the manufacturer of a device from making any change in design, components, manufacturing or labeling that

might impact the device's safety and effectiveness without first securing the FDA's review and consent. **(Exhibit D)**.

33. Since granting PMA approval, the FDA has subjected the PRIZM 2 to post-marketing requirements. CPI submitted Annual Reports for the PRIZM 2 to the FDA on August 17, 2001; August 16, 2002; August 19, 2003; February 16, 2005, September 21, 2005, and July 17, 2006.

34. At all times since PMA approval, CPI has met all post-marketing requirements and has maintained approval of the PRIZM 2 as a Class III medical device in compliance with federal regulations and with continuing FDA supervision.

Further affiant saith not.

Brian Novak, Manager of Regulatory Affairs
Cardiac Pacemakers, Inc.

SUBSCRIBED AND SWORN TO BEFORE ME this 16th day of August, 2006.

Notary Public

My commission expires:

January 31, 2010

TERESE TIESO
Notary Public
Minnesota
My Commission Expires January 31, 2010