Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
	)	File No. EB-06-SE-247
Boston Scientific Corporation	)	NAL/Acct. No. 200732100007
	)	FRN # 0015229735

ORDER

Adopted: December 5, 2006 **Released: December 7, 2006**

By the Chief, Enforcement Bureau:

1. In this Order, we adopt the attached Consent Decree entered into between the Enforcement Bureau and the Cardiac Rhythm Management business unit of Boston Scientific Corporation (hereinafter "Boston Scientific CRM"). The Consent Decree terminates an investigation initiated by the Enforcement Bureau into the use of the 90-110 kHz band by certain implantable cardiac devices manufactured and sold by Boston Scientific CRM, and the extent to which these devices have obtained the required equipment authorizations in compliance with Section 302(b) of the Communications Act of 1934, as amended ("Act")[1] and Parts 2 and 15 of the Commission's rules.[2]

2. The Enforcement Bureau and Boston Scientific CRM have negotiated the terms of a Consent Decree that would resolve this matter and terminate the investigation. A copy of the Consent Decree is attached hereto and incorporated by reference.

3. Based on the record before us, we conclude that no substantial or material questions of fact exist with respect to this matter as to whether Boston Scientific CRM possesses the basic qualifications, including those related to character, to hold or obtain any FCC license or authorization.

4. After reviewing the terms of the Consent Decree, we find that the public interest would be served by adopting the Consent Decree and terminating the investigation.

5. Accordingly, **IT IS ORDERED** that, pursuant to Section 4(i) of the Act,[3] and Sections 0.111 and 0.311 of the Commission's rules,[4] the attached Consent Decree **IS ADOPTED**.

6. **IT IS FURTHER ORDERED** that the Enforcement Bureau's investigation **IS TERMINATED**.

7. **IT IS FURTHER ORDERED** that Boston Scientific CRM shall make its voluntary contribution to the United States Treasury, as specified in the Consent Decree, by credit card through the Commission's Debt and Credit Management Center at (202) 418-1995, or by mailing a check or similar instrument, payable to the order of the Federal Communications Commission, to the Federal

[1] 47 U.S.C. § 302a(b).

[2] 47 C.F.R. § 2.1 *et seq.* and § 15.101 *et seq.*

[3] 47 U.S.C. § 154(i).

[4] 47 C.F.R. §§ 0.111, 0.311.

Communications Commission, P.O. Box 358340, Pittsburgh, PA 15251-8340. Payment by overnight mail may be sent to Mellon Bank/LB 358340, 500 Ross Street, Room 1540670, Pittsburgh, PA 15251. Payment by wire transfer may be made to ABA Number 043000261, receiving bank Mellon Bank, and account number 911-6106.

8. **IT IS FURTHER ORDERED** that a copy of this Order and Consent Decree shall be sent by first class mail and certified mail, return receipt requested, to Ronald Reimann, Jr., Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, and to Robert J. Ungar, Esq. and Terry G. Mahn, Esq., Fish & Richardson, P.C., 1425 K Street, N.W., 11th Floor, Washington, DC 20005-3500.

FEDERAL COMMUNICATIONS COMMISSION

Kris Anne Monteith
Chief, Enforcement Bureau

CONSENT DECREE

The Enforcement Bureau ("Bureau") of the Federal Communications Commission (the "FCC" or "Commission") and the Cardiac Rhythm Management business unit of Boston Scientific Corporation, (hereinafter "Boston Scientific CRM"), by their authorized representatives, hereby enter into this Consent Decree for the purpose of terminating the Bureau's investigation into whether certain Boston Scientific CRM implantable cardiac devices ("ICDs") meet the requirements of Section 302(b) of the Communications Act of 1934, as amended (the "Act"),[5] and Parts 2 and 15 of the Commission's rules. [6]

Background

1. Boston Scientific CRM manufactures and markets ICDs designed to manage heart rhythms. ICDs in three Boston Scientific CRM product families – the PDM, PD2 and Contak Renewal TR/2 families – use inductive coupling to provide information about heart function to external monitoring devices. Issues concerning radiofrequency ("RF") emissions in the 90-110 kHz restricted frequency band produced as a by-product of the inductive coupling function led Boston Scientific CRM to seek the advice, beginning in 2004, of the staff of the Office of Engineering and Technology ("OET") and the National Telecommunications and Information Administration ("NTIA") of the Department of Commerce. Boston Scientific CRM met with the Enforcement Bureau staff on March 23, 2006. As a result of that meeting, Boston Scientific CRM submitted a petition for waiver on June 6, 2006 to allow usage of the 90-110 kHz band for inductive telemetry in existing and future products until engineering changes could be made.[7]

2. On June 27, 2006, the Bureau issued a Letter of Inquiry ("LOI") to Boston Scientific CRM initiating an investigation into whether Boston Scientific CRM's inductively coupled ICDs produced RF emissions in the 90-110 kHz band and the extent to which Boston Scientific CRM had obtained Commission authorizations for its ICDs. Boston Scientific CRM submitted its response to the LOI on August 10, 2006.

3. The Bureau's investigation did not relate to the safety or efficacy of the Boston Scientific CRM ICDs. Rather, the investigation was limited to use of the 90-110 kHz restricted band and whether Boston Scientific CRM had the required equipment authorizations for the inductive (magnetic) telemetry systems in certain of Boston Scientific CRM's ICDs.

Definitions

4. For purposes of this Consent Decree, the following definitions shall apply:

   a. "Act" means the Communications Act of 1934, as amended, 47 U.S.C. §§ 151 *et seq*.

   b. "Adopting Order" means an Order of the Bureau adopting the terms and conditions of this Consent Decree.

   c. "Bureau" means the Enforcement Bureau of the Federal Communications Commission.

[5] 47 U.S.C. § 302a(b).

[6] 47 C.F.R. § 2.1 *et seq.* and § 15.101 *et seq*.

[7] *Respironics, Inc. and Boston Scientific Corporation*, Order, ET Docket No. 05-331, DA 06-2316 (OET, released November 16, 2006).

d. "Commission" and "FCC" mean the Federal Communications Commission.

e. "Effective Date" means the date on which the Bureau releases the Adopting Order.

f. "Investigation" means the investigation commenced by the Bureau's June 27, 2006 Letter of Inquiry[8] regarding Boston Scientific CRM's use of the 90-110 kHz band and whether it had obtained required equipment authorizations for its ICDs.

g. "Parties" means Boston Scientific CRM and the Bureau.

h. "Rules" means the Commission's Rules found in Title 47 of the Code of Federal Regulations.

i. "Boston Scientific CRM" means the Cardiac Rhythm Management business unit of Boston Scientific Corporation, including affiliates, subsidiaries and/or successors.

Terms of Agreement

5. The Parties agree that the provisions of this Consent Decree shall be subject to final approval by the Bureau by incorporation of such provisions by reference in the Adopting Order.

6. Boston Scientific CRM agrees that the Bureau has jurisdiction over it and the subject matter contained in this Consent Decree and the authority to enter into and adopt this Consent Decree.

7. The Parties agree and acknowledge that this Consent Decree shall constitute a final settlement of the Investigation between Boston Scientific CRM and the Bureau. In express reliance on the covenants and representations contained herein, the Bureau agrees to terminate the Investigation. In consideration for the termination of this Investigation and in accordance with the terms of this Consent Decree, Boston Scientific CRM agrees to the terms, conditions and procedures contained herein.

8. The Parties agree that this Consent Decree shall become binding on the Parties on the Effective Date. Upon release, the Adopting Order and this Consent Decree shall have the same force and effect as any other final order of the Commission and any violation of the terms or conditions of this Consent Decree shall constitute a violation of a Commission order.

9. The Parties agree that this Consent Decree does not constitute either an adjudication on the merits or a factual or legal finding or determination regarding any compliance or noncompliance by Boston Scientific CRM with the requirements of the Act or the Commission's rules or orders. The Parties agree that this Consent Decree is for settlement purposes only and that by agreeing to this Consent Decree, Boston Scientific CRM does not admit or deny any noncompliance, violation, or liability associated with or arising from its actions or omissions involving the Act or the Commission's rules that are the subject of this Consent Decree.

10. Boston Scientific CRM agrees to make a voluntary contribution to the United States Treasury, without further protest or recourse, in the amount of $25,000 within thirty (30) calendar days after the Effective Date of the Adopting Order. This voluntary payment does not constitute a fine or penalty for, or admission of, a violation of any law. Such contribution shall be made by credit card through the Commission's Debt and Credit Management Center at (202) 418-1995, or by mailing a check or similar instrument, payable to the order of the Federal Communications Commission, to the Federal Communications Commission, P.O. Box 358340, Pittsburgh, PA 15251-8340. Payment by overnight

[8] *See* Letter from Kathryn S. Berthot, Deputy Chief, Spectrum Enforcement Division, Enforcement Bureau, to Terry G. Mahn, Esq. and Robert J. Ungar, Esq., Counsel for Boston Scientific Corporation (June 27, 2006).

mail may be sent to Mellon Bank /LB 358340, 500 Ross Street, Room 1540670, Pittsburgh, PA 15251. Payment by wire transfer may be made to ABA Number 043000261, receiving bank Mellon Bank, and account number 911-6106. The payment should reference NAL/Acct. No. 200732100007 and FRN # 0015229735.

11. Boston Scientific CRM has begun and will continue to implement an FCC Regulatory Compliance Plan to ensure compliance with the Act, the Rules, and the Commission's orders. Specifically, Boston Scientific CRM has taken and will continue to take the following steps:

- **Engineering Compliance Manager.** Boston Scientific CRM has appointed an Engineering Compliance Manager with oversight of FCC regulatory compliance for CRM devices, including verification and certification, input and involvement in engineering decisions, and access to experienced outside legal counsel with expertise in FCC compliance matters. Boston Scientific CRM's Engineering Compliance Manager has also been involved in affecting procedural and systemic changes to ensure FCC compliance. Boston Scientific also has a Chief Compliance Officer for its Cardiac Rhythm Management and Cardiac Surgery businesses ("CRM/CS CCO"). The CRM/CS CCO is a senior-level official who has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The CRM/CS CCO is charged with the responsibility for developing, operating and monitoring the CRM compliance program, including providing an internal line of communication to allow confidential reports of potential violations. The Chief Compliance Officer coordinates with the Engineering Compliance Manager on engineering compliance matters.

- **Staffing and Training.** Boston Scientific CRM has established an RF technology engineering group and trained them on FCC licensing and compliance, including verification and certification testing. Engineers in the group coordinate with the Engineering Compliance Manager and are involved in a variety of matters relating to radio frequency technology, including design evaluation, testing, and regulatory submissions.

- **Product Approval and Distribution.** Boston Scientific CRM's product approval process and distribution process for ICDs are being enhanced to further ensure FCC compliance, including verification and certification testing of all product designs. Specifically:

    - The Product Development Process is being formally modified to add a required procedure to ensure all electromagnetic energy transmission testing is completed and passed prior to product design approval. This includes verification or certification testing being certified by the Engineering Compliance Manager in writing that the product is compliant with all FCC regulations. This process modification will be complete by December 31, 2006.

    - The Product Release Approval (PRA) process is being formally modified to include electromagnetic compliance licensing approvals to prevent product being sold until the Engineering Compliance Manager has certified in writing that the product has all its necessary regulatory approvals. This process modification will be complete by December 31, 2006.

- **Technical Design Requirement.** Boston Scientific CRM has established a Technical Requirement for ICDs specifying compliance with the 90-110 kHz

restricted band regulation for all future products. This Requirement will be mandated in future Boston Scientific CRM product definitions and specifies device testing as part of the product development test strategy.

- **Interference Complaints.** Boston Scientific CRM has established a process for handling any interference complaints. Specifically, Boston Scientific CRM has ensured that any interference complaints are handled appropriately by Boston Scientific CRM's Technical Services group with support from Boston Scientific CRM's radio frequency engineering group.

- **Review and Monitoring.** Boston Scientific CRM will review the FCC Compliance Plan annually to ensure that it is maintained in a proper manner and continues to address the objectives set forth therein.

12. The Bureau agrees that, in the absence of new material evidence, it shall not on its own motion or in response to third-party objection, initiate any inquiries, investigations, forfeiture proceedings, hearings, or other sanctions or actions against Boston Scientific CRM based in whole or in part on the Investigation. The Bureau also agrees that, in the absence of new material evidence, it will not initiate or recommend to the Commission any new proceeding, formal or informal, against Boston Scientific CRM regarding the matters that were the subject of the Investigation. The Bureau further agrees that, in the absence of new material evidence, it will not use the facts developed in the Investigation through the Effective Date to initiate on its own motion, or recommend to the Commission, any proceeding, formal or informal, or take any action on its own motion against Boston Scientific CRM with respect to Boston Scientific CRM's basic qualifications to hold Commission licenses or authorizations.

13. Boston Scientific CRM's decision to enter into this Consent Decree is expressly contingent upon the Bureau's issuance of an Adopting Order that is consistent with this Consent Decree, and which adopts the Consent Decree without change, addition or modification.

14. Provided the Bureau issues an Adopting Order adopting the Consent Decree without change, addition or modification, the Parties waive any and all rights they may have to seek administrative or judicial reconsideration, review, appeal or stay, or to otherwise challenge or contest the validity of this Consent Decree and the Adopting Order.

15. If either Party (or the United States on behalf of the Commission) brings a judicial action to enforce the terms of the Adopting Order, neither Boston Scientific CRM nor the Commission shall contest the validity of the Consent Decree or the Adopting Order, and Boston Scientific CRM and the Commission will waive any statutory right to a trial de novo with respect to the issuance of the Adopting Order and shall consent to a judgment incorporating the terms of this Consent Decree.

16. In the event that this Consent Decree is rendered invalid by a court of competent jurisdiction, it shall become null and void and may not be used in any manner in any legal proceeding.

17. By this Consent Decree, Boston Scientific CRM neither waives nor alters its right to assert and seek protection from disclosure of any privileged or otherwise confidential and protected documents and information, or to seek appropriate safeguards of confidentiality for any competitively sensitive or proprietary information.

18. The Parties agree that each is required to comply with each individual condition of this Consent Decree. Each specific condition is a separate condition of the Consent Decree as approved. To the extent that Boston Scientific CRM fails to satisfy any condition, in the absence of Commission alteration of the condition, it will be deemed noncompliant and may be subject to possible future enforcement action with respect to such failure to satisfy the condition.

19. The Parties agree that if any provision of this Consent Decree conflicts with any subsequent rule, order of general applicability or other decision of general applicability adopted by the Commission, that provision will be superceded by such Commission rule or order.

20. Boston Scientific CRM waives any rights it may have under any provision of the Equal Access to Justice Act, 5 U.S.C. § 504 and 47 C.F.R. § 1.1501 *et seq*., relating to the matters addressed in this Consent Decree.

21. This Consent Decree cannot be modified without the advance written consent of both Parties.

22. The Parties agree that the requirements of this Consent Decree shall expire twenty-four (24) months from the Effective Date.

23. This Consent Decree may be signed in counterparts.

For: Boston Scientific Corporation

_____
William F. McConnell, Jr.
Senior Vice President, Administration

Date: _____

For: Enforcement Bureau
Federal Communications Commission

_____
Kris Anne Monteith
Chief, Enforcement Bureau

Date: _____