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

In the matter of	)	
	)	
Respironics, Inc. and Boston Scientific	)	
Corporation	)	ET Docket No. 05-331
	)	
Requests for Waiver of Section 15.205 of the	)	
Commission's Rules to Permit the Marketing and	)	
Operation of Certain Medical Communications	)	
Devices that Operate in the 90-110 kHz band	)	

ORDER

Adopted: July 13, 2009 **Released: July 14, 2009**

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. By this order, we grant a request by Boston Scientific Corporation to extend the existing waiver of Section 15.205 of our rules for its "Contak Renewal TR" product line of implanted cardiac medical devices that operate in the 90-110 kHz band.[1] The present waiver is scheduled to expire on November 16, 2009. The extension that we grant herein will permit the continued manufacture and marketing of these devices until the *earlier* of (i) May 8, 2011, or (ii) 90 days after the date on which the Food and Drug Administration (FDA) approves Boston Scientific's FCC rules-compliant replacement for the Contak Renewal TR devices.

2. Because cardiac patients will be afforded with the continued availability of the salutary health benefits provided by these devices, and because the risk of harmful interference to other authorized operations in the band is extremely small, we conclude that good cause exists for extending the existing waiver and that the public interest will thereby be served.[2]

II. BACKGROUND

3. Boston Scientific manufactures several lines of implantable cardiac medical devices, including cardiac resynchronization therapy devices (the Contak Renewal TR family), pacemakers (the "PDM" family), and cardioverter defibrillators (the "PD2" family). As presently designed, these devices rely entirely upon inductive coupling to download data from, and modify the operational settings of, the implanted devices.[3] Because this inductive coupling technique produces fundamental emissions in the

[1] *See* "Request for Extension of Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on March 6, 2009.

[2] *See WAIT Radio v. FCC*, 459 F.2d,1203, 1207 (D.C. Cir. 1972).

[3] With the inductive coupling technique used by these devices, data transfer takes place by placing an external "wand" reader over the patient's chest within inches of the implant. The wand and implant then communicate by sending and receiving extremely low level transmissions.

90-110 kHz restricted band, these devices do not comply with the restricted band provisions of Section 15.205 our rules.[4]

4. On June 6, 2006, Boston Scientific requested a waiver of Section 15.205 of the Commission's rules for its Contak Renewal TR, PDM, and PD2 product lines of cardiac devices described above.[5] In support of this request, Boston Scientific stated that it was in the process of developing "next generation" devices (the "Cognis," "Teligen," and "Ingenio" families) that would also use inductive coupling on frequencies in the 90-110 kHz band, but only to initiate a communications session or as a backup means of data communications.[6] Boston Scientific further argued that a waiver of Section 15.205 would permit it sufficient time to exit the 90-110 kHz band in an orderly manner (while it develops yet newer devices that would rely solely on transmissions in the 900 MHz band).[7]

5. On November 16, 2006, the Chief of the Office of Engineering and Technology (OET), by delegated authority, issued an Order (*Waiver Order*) granting a waiver of Section 15.205 of the Rules.[8] Pursuant to the *Waiver Order*, Boston Scientific was permitted to continue the manufacture and marketing of the Contak Renewal TR devices for three years, and the PDM and PD2 devices for two years, respectively, starting from release of the *Waiver Order*; or, in each case, until six months after final regulatory approval of the next generation Cognis, Teligen and Ingenio devices, whichever came first. However, with respect to the next generation Cognis, Teligen and Ingenio devices, the *Waiver Order* permitted their manufacture and marketing for only three years after the release date of the Order instead of the six years from Food and Drug Administration ("FDA") approval that was requested by Boston Scientific.

6. Subsequently, on July 11, 2007, in response to a petition for reconsideration filed by Boston Scientific,[9] the Chief of OET issued a further order (*Waiver Modification Order*) that modified the terms of the original *Waiver Order*. This modification permitted Boston Scientific to continue the manufacture and marketing of its next generation Cognis and Teligen series of devices for three years after FDA approval.[10] Boston Scientific has since informed us that FDA approval was received for these devices on

[4] 47 C.F.R. §15.205. Under Section 15.205 of the Commission's rules for unlicensed radio devices, intentional radiators generally are not permitted to operate in certain sensitive or safety-related frequency bands that are designated as "restricted bands." The restricted bands listed in Section 15.205 are bands employed by radio services that function, as a nature of their operation or use, with extremely low signal levels. These systems may be passive, such as radio astronomy, or active, such as satellite down links.

[5] *See* "Petition for Waiver" (June 6, 2006).

[6] *See id*. at 5 and 12.

[7] *See id*. at 3.

[8] *See* "In the Matter of Respironics, Inc. and Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the marketing and operation of certain medical communications devices that operate in the 90-110 kHz band," 21 FCC Rcd 13450, Order, ET Docket No. 05-331, DA 06-2316 (2006) (*Waiver Order*). The Respironics waiver is not at issue herein.

[9] *See* "Petition for Reconsideration" in ET Docket No. 05-331, filed by Boston Scientific on December 18, 2006.

[10] *See* "In the Matter of Respironics, Inc. and Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the marketing and operation of certain medical communications devices that operate in the 90-110 kHz band," 22 FCC Rcd 12881, Order, ET Docket No. 05-331, DA 07-3160 (2007) (*Waiver Modification Order*). Boston Scientific did not seek a modification of the waiver period for the Ingenio product line, as it had begun to redesign the product to emit outside of the 90-110 kHz band. *See id*. at n.4. *See also,* "Petition for Reconsideration" (December 18, 2006) at n.13.

May 8, 2008.[11] Thus, given the subsequent approval by FDA, the waiver for the Cognis and Teligen devices will expire on May 8, 2011.

7. On March 6, 2009, Boston Scientific filed the subject "Request For Extension Of Waiver" by which it seeks an extension of our original *Waiver Order* as it applies to the Contak Renewal TR devices. As presently set forth, the waiver of Section 15.205 of the Rules for the Contak Renewal TR devices would expire on November 16, 2009. Boston Scientific now asks that this waiver be set to expire on the *earlier* of (i) May 8, 2011, or (ii) 90 days after the date on which the FDA approves the fully rules-compliant replacements for the Contak Renewal TR.[12]

8. In support of this request, Boston Scientific states that, since grant of the original *Waiver Order*, it has undertaken a major redesign of its next generation "Ingenio" product line so that, going forward, they will use inductive telemetry emitting on frequencies entirely outside of the 90-110 kHz band – and, thus, will be fully compliant with our rules.[13] Relevant to our discussion here, this will include a new product line to be known as the "Cognis CRT-P" which Boston Scientific identifies as the replacement for the Contak Renewal TR devices covered by the existing waiver.[14]

9. Boston Scientific further states that this redesign effort has taken substantially longer than initially anticipated.[15] More specifically, it claims that the development period has been lengthened by unexpected complexities related to the inductive telemetry subsystem that will enable these devices to emit only on frequencies outside of the 90-110 kHz band. Boston Scientific further argues that FDA approval must subsequently be obtained after the design reliability verification phase for these devices has been completed.[16] The FDA approval process, Boston Scientific informs us, typically requires at least six months. Based on these considerations, Boston Scientific now estimates that it will be able to commence manufacture and distribution of the new devices by, or before, May 2011.[17]

III. DISCUSSION

10. We find that the particular circumstances that supported the grant of the previous *Waiver Order,* as well as the subsequent *Waiver Modification Order*, also support our grant herein of an extension of the waiver for the Contak Renewal TR devices as requested by Boston Scientific.

11. As we stated in the *Waiver Modification Order,* these waivers present an unusual and compelling public interest situation in which patients and their caregivers rely upon the devices at issue for health- and life-critical purposes.[18] Thus, while product development delays – such as those described above – might not provide sufficient justification standing alone, we also determine that the especially critical benefits provided by these devices do present an overriding public interest basis for the requested relief.[19] Furthermore, we note that the latest version Ingenio replacements for the Contak Renewal TR

[11] *See* "Petition for Waiver" (June 6, 2006) at 5.

[12] *See* "Request for Extension of Waiver" (March 6, 2009).

[13] *See id.* at 5-7. According to Boston Scientific, earlier versions of these next generation devices would have continued to emit radiation in the 90-110 kHz band.

[14] *See id*. at n.4

[15] *See id.* at 6.

[16] *See id.*

[17] *See id.*

[18] *See Waiver Modification Order, supra,* at para. 10.

[19] *See id.*

that Boston Scientific cites in support of its extension request will eliminate radiation in the 90-110 kHz band entirely, and thus would be fully compliant with our rules. By comparison, the previous versions of the "next generation" devices that Boston Scientific had under development when we granted the original waiver would have continued to emit radiation in the 90-110 kHz band. We acknowledge Boston Scientific's efforts to transition its production to fully compliant devices (instead of interim, non-compliant devices) and conclude that it is reasonable and appropriate for us to accommodate the additional development delays that have occurred in furtherance of achieving this desirable goal. Accordingly, consistent with our earlier actions with respect to this matter, we find good cause to extend the waiver of Section 15.205 of our rules for the Contak Renewal TR devices.

12. As a result of our action in this Order, patients will continue to benefit from the availability of important health- and life-critical medical implant technologies offered by these cardiac devices pending the availability of the newer rules-compliant devices that are expected in the near future. Furthermore, as we have previously determined, these cardiac devices present an extremely small risk of harmful interference to other authorized operations, such as LORAN-C, in the 90-110 kHz band.[20] Given the remote likelihood of such interference, we find that grant of this waiver will not contravene the underlying purpose of Section 15.205 of the Rules. Finally, granting the requested relief will align the latest possible expiration of the Contak Renewal TR waiver with the date the modified waivers for the next generation of Cognis and Teligen series of devices expire: May 8, 2011.

IV. ORDERING CLAUSES

13. Accordingly, pursuant to Sections 4(i), 302, 303(e), 303(r) and 405 of the Communications Act of 1934, as amended (47 U.S.C. §§ 154(i), 302, 303(e), 303(r) and 405), and Section 1.106(a)(1) of the Commission's rules (47 C.F.R. § 1.106(a)(1)), IT IS ORDERED that the "Contak Renewal TR" product line of cardiac medical devices may continue to be manufactured and marketed until the *earlier* of (i) May 8, 2011 - or (ii) 90 days after the date on which the Food and Drug Administration (FDA) approves Boston Scientific's FCC rules-compliant replacement for the Contak Renewal TR devices.

14. It is FURTHER ORDERED that Boston Scientific MUST SHOW that it has obtained FDA approval, including date of such approval, as part of its submission for equipment certification of the FCC rules-compliant replacement for the Contak Renewal TR devices.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp, Chief
Office of Engineering and Technology

[20] As stipulated in the original *Waiver Order*, *supra,* the temporary waiver embodied by this Order only applies to the constraints on emissions in the restricted frequency bands as specified in Section 15.205 of the Commission's rules. This waiver does not provide relief of the requirements of Section 15.5(b). Specifically, this includes the requirement that interference to the subject Boston Scientific Corporation products that may be caused by the operation of a LORAN-C radio station must be accepted. *See Waiver Order, supra,* at para. 9.