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

In the Matter of	)	
	)	
Boston Scientific	)	
Corporation	)	ET Docket No. 05-331
	)	
Request 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: August 22, 2011 **Released: August 23, 2011**

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. By this Order, we grant a request by Boston Scientific Corporation (Boston Scientific) to extend the existing waiver of Section 15.205 of our rules for its Contak Renewal TR, Cognis, and Teligen cardiac devices.[1] Granting Boston Scientific's request will permit these devices to continue to use the 90-110 kHz band while Boston Scientific finalizes the development and introduction of replacement devices that will not operate in that band. The present waivers are scheduled to expire on December 31, 2011, and the extension granted herein will permit the continued manufacture and marketing of the subject devices until June 30, 2013, or until one year after the Food and Drug Administration (FDA) approves each device, whichever comes first.

2. This further extension is needed due to unanticipated delays in the completion of product development for the respective devices or in the approval of the replacement devices by the FDA. Because the health benefits provided by these devices will continue to be available to cardiac patients that have come to rely on them, and because the risk of harmful interference to other authorized operations in the band is extremely small, we conclude that good cause exists, and the public interest would be served by, extending the existing waiver.[2]

II. BACKGROUND

3. Boston Scientific manufactures several lines of implantable cardiac medical devices, including cardiac resynchronization therapy devices (the Contak Renewal TR devices), cardiac resynchronization devices with pacemakers (the Cognis devices), and cardioverter defibrillators (the Teligen devices). As currently designed, these devices rely on inductive coupling to initiate communication sessions that download data from, and modify the operational settings of, the implanted

[1] *See* "Request for Further Extension of Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on May 13, 2010.

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

devices and to serve as a backup communications link.[3] Because this inductive coupling technique produces fundamental emissions in the 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 first requested a waiver of Section 15.205 of the Commission's rules for its Contak Renewal TR devices and the precursors of the Cognis and Teligen devices described above, the PDM and PD2 families. The PDM and PD2 devices also used inductive coupling at 90-110 kHz for their entire communications sessions, and at the time of the June 6, 2006 waiver request, Boston Scientific was well into the process of developing the Cognis and Teligen devices, which rely on inductive coupling in the 90-110 kHz band only for the initiation phase of the communications, thus significantly reducing its encroachment on the restricted 90-110 kHz band, and had begun development of devices that would rely solely on transmissions in the 900 MHz band, as permitted by our rules. Boston Scientific 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 developed the fully-compliant devices.

5. On November 16, 2006, the Chief of the Office of Engineering and Technology (OET), by delegated authority, issued an Order granting a waiver of Section 15.205 of the Rules.[5] Pursuant to the *Waiver Order*, Boston Scientific was permitted to continue the manufacture and marketing of the Contak Renewal TR devices for three years from the release date of the *Waiver Order* or until six months after final regulatory approval of the Cognis and Teligen devices, whichever came first. With respect to the Cognis and Teligen devices, the *Waiver Order* permitted their manufacture and marketing for three years after the release date of the Order.[6] This time frame was intended to minimize the time during which the noncompliant devices would be used before the new, fully compliant products would enter the market.[7]

6. Subsequently, on July 11, 2007, in response to a petition for reconsideration filed by Boston Scientific,[8] 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

[3] *See* "Petition for Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on June 6, 2006, at pages 5 and 12. The inductive coupling technique used by these devices initiates a data transfer by placing an external "wand" reader over the patient's chest within centimeters of the implant. The wand and implant then communicate on other (unrestricted) frequencies by sending and receiving data that provide information stored in the device's memory to allow physicians to monitor a patent's cardiac events and the functioning of the implanted system. In the event the primary communications channel does not function properly, the initial coupling link at 90-110 kHz can also be used to transfer this data.

[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 downlinks.

[5] *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.

[6] Boston Scientific had requested that the waiver expire six years after FDA approval of the Cognis and Teligen devices.

[7] *Waiver Order, supra,* at para. 13.

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

approval, rather than three years from the date of the Order.[9] The FDA granted approval for these devices on May 8, 2008, which meant that the waiver for the Cognis and Teligen devices was set to expire on May 8, 2011.

7. On July 14, 2009, the Chief of OET issued a further waiver (*Contak TR Waiver Modification Order*) granting a March 6, 2009, Boston Scientific request to extend the expiration date of the waiver for the Contak TR to the same date as the new waiver expiration date for the Cognis and Teligen devices.[10] On September 15, 2010, the Chief of OET issued another waiver extension for the Contak TR, Cognis, and Teligen devices, until December 31, 2011, in light of unplanned design enhancements and unanticipated delays in bringing the next generation, compliant devices to market.[11]

8. Boston Scientific now requests a further extension of the waiver for all three of its current product lines, *i.e.*, the Contak Renewal TR, Cognis, and Teligen devices, until the earlier of twelve months after FDA approval for each device, or June 30, 2013, whichever is sooner. In support of this request, Boston Scientific states that, despite investing millions of dollars in the redesign of its products to comply with FCC regulations, it has experienced unanticipated delays as a result of unplanned but necessary further design enhancements. It submits that it is now in the final stages of development for the next generation, compliant products but that the time remaining in its current waiver is not adequate to complete reliability testing, FDA review and approval, and introduction of the new products into the medical community. It expects FDA approval could take until the middle of 2012, and needs time for an orderly introduction of and transition to the new systems.

III. DISCUSSION

9. We find that the particular circumstances that supported the grant of the previous *Waiver Order*, the subsequent *Waiver Modification Order*, and the related *Contak TR Waiver Modification Order* also support our grant herein of a relatively short extension of the waivers for the Contak Renewal TR, Cognis, and Teligen devices as requested by Boston Scientific.

10. As we stated in the previous *Orders* involving these products, these waivers present an unusual and compelling public interest situation in which patients and their caregivers rely on the devices at issue for health- and life-critical purposes.[12] We acknowledge Boston Scientific's continued efforts to transition its production to fully compliant devices and conclude that, in furtherance of achieving this desirable goal, it is reasonable and appropriate for us to accommodate the additional development delays

[9] *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*).

[10] "Request for Extension of Waiver" (March 6, 2009). Boston Scientific asked for and was granted an extension until the *earlier* of (i) May 8, 2011, or (ii) 90 days after the FDA approval date for fully rules-compliant replacements for the Contak Renewal TR. 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, *Order* in ET Docket No. 05-331, 24 FCC Rcd 9089 (Office of Engineering and Technology, 2009). The FDA did not grant approval by May 8, 2008, and consequently May 8, 2011 became the default date for expiration of the waivers.

[11] 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, *Order* in ET Docket No. 05-331, 25 FCC Rcd 13143 (Office of Engineering and Technology, 2010) (*Waiver Extension Order*).

[12] *See Waiver Modification Order, supra,* at para. 10.; *Contak TR Waiver Modification Order, supra***,** at paras. 11, 12; *Waiver Extension Order, supra,* at para. 10.

that have occurred. The extension granted herein will ensure that the treatment benefits provided by these devices will continue to be available to patients until FCC-compliant replacements can be brought to market in an orderly manner, and the critical benefits provided by these devices continue to present a significant public interest basis for the requested relief. As we have previously determined, these cardiac devices present an extremely small risk of harmful interference to other authorized operations.[13] 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. Because these devices are already operating pursuant to the *Waiver Extension Order*, there are no significant costs associated with extending the waiver. This decision remains consistent with our earlier determination to minimize the time for which noncompliant devices would be used before new, fully compliant products would enter the market.[14]

11. 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, Cognis, and Teligen devices as requested.

IV. ORDERING CLAUSES

12. 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 Boston Scientific may continue to manufacture and market the "Contak Renewal TR," "Cognis," and "Teligen" product lines of cardiac medical devices until the earlier of twelve months after FDA approval for each device or June 30, 2013, whichever comes first for each device.

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

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp, Chief
Office of Engineering and Technology

[13] As stipulated in the original *Waiver Order*, *supra,* the *Contak TR Waiver Modification Order, supra*, and the *Waiver Extension 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) that the subject devices do not cause interference to and must accept interference from other authorized stations, radiators or equipment. *See Waiver Extension Order, supra* at n. 13. (We do note that LORAN-C operations (in the 90-110 kHz band) have been discontinued. See, http://www.navcen.uscg.gov/?pageName=loranMain.)

[14] *See,* para. 5, *supra*, n.7, *supra*.