Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

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	)	ET Docket No. 05-331

REQUEST FOR LIMITED FURTHER EXTENSION OF WAIVER

Karen Brinkmann
Robin Tuttle
KAREN BRINKMANN PLLC
555 Eleventh Street, NW
Mail Station 07
Washington, D.C. 20004-1304
(202) 365-0325
KB@KarenBrinkmann.com

Counsel for Boston Scientific Corporation

August 8, 2012

SUMMARY

Boston Scientific Corporation ("Boston Scientific") manufactures and distributes a life-enhancing implantable medical device, the Cognis device, which uses an inductive telemetry system that generates extremely low levels of radio frequency ("RF") emissions in the 90-110 kHz band to communicate with monitoring equipment at a physician's office. The Cognis device is an implantable cardiac device (like a pacemaker or defibrillator) that has been part of an ongoing clinical trial since 2010, in which Boston Scientific is collecting physiologic data related to patients' worsening heart failure to support the development of device features designed to reduce health care system costs and enhance patient outcomes. A fully successful completion of the clinical trial depends on the continued manufacture, sale, and use of the Cognis device, as well as sufficient patient participation in the trial, which is subject to physician involvement and patient availability, both of which are outside the control of Boston Scientific.

The Cognis device emits RF in the 90-110 kHz band only when the patient is in the physician's office, infrequently and for a limited period of time in each instance. However, the Commission's rules provide priority to the LORAN radionavigation system in this band, and this band is not available for unlicensed use under Section 15.205 of the Commission's rules. Therefore, Boston Scientific previously requested and received a waiver of the Commission's rules to permit the continued manufacture, sale, and use of its legacy Cognis device. As extended by Office of Engineering & Technology, on delegated authority from the Commission, that waiver will expire on November 17, 2012. Despite diligent efforts to complete the clinical trial that involves use of the Cognis device, Boston Scientific seeks a limited further extension of the existing waiver granted for continued manufacture, sale, and use of the Cognis device until

December 31, 2013, by which time full enrollment in the clinical trial is expected to be completed.

Grant of the requested waiver extension will serve the public interest. Boston Scientific expects the results of the clinical trial to improve management of patients with worsening heart failure, minimizing required hospitalizations, and ultimately reducing related economic burdens on the medical system. Boston Scientific hopes to use the clinical trial results to develop features designed to help reduce patient hospitalizations by treating worsening heart failure before overt decompensation that leads to necessary hospitalization. The significant amount of work already completed by the clinical trial would be undermined and opportunities for improving patient treatment would be impaired or delayed if Boston Scientific were required to discontinue use of the Cognis device at the current waiver expiration date. Due to the limited and localized use of the 90-110 kHz band frequencies by the implanted device in a medical facility, the limited extension that Boston Scientific requests is not anticipated to adversely affect any other users of the band, and a limited extension of the waiver term is justified.

TABLE OF CONTENTS

Page

SUMMARY i

I. BACKGROUND 2

II. SPECIAL CIRCUMSTANCES EXIST WHICH JUSTIFY A LIMITED WAIVER EXTENSION 5

III. THE PUBLIC INTEREST WILL BE SERVED BY EXTENDING THE WAIVER, AND STRICT COMPLIANCE WITH THE RULE WOULD BE INCONSISTENT WITH THE PUBLIC INTEREST 9

IV. CONCLUSION 11

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

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	)	ET Docket No. 05-331

REQUEST FOR LIMITED FURTHER EXTENSION OF WAIVER

Boston Scientific Corporation ("Boston Scientific") hereby requests a limited further extension of the waiver of Section 15.205(a) of the Commission's rules, granted in the 2011 Waiver Modification Order in the above-referenced proceeding, permitting the continued manufacture, sale, and use of a certain life-enhancing, implantable medical device – the Cognis device – that operates in the 90-110 kHz band.[1] The current waiver for the Cognis device expires on November 17, 2012.[2] Boston Scientific only seeks an extension for its Cognis

---

[1] *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, 21 FCC Rcd 13450 (2006) ("Waiver Order"), *modified*, Order, 22 FCC Rcd 12881 (Office of Eng. & Tech. 2007) ("Waiver Modification Order"), *modified*, Order, 24 FCC Rcd 9089 (Office of Eng. & Tech. 2009) ("Contak Renewal TR Waiver Modification Order"), *modified*, Order, 25 FCC Rcd 13143 (Office of Eng. & Tech. 2010) ("2010 Waiver Modification Order"), *modified*, Order, 26 FCC Rcd 11405 (Office of Eng. & Tech. 2011) ("2011 Waiver Modification Order").

[2] The 2011 Waiver Modification Order addressed a waiver request for three cardiac devices – Cognis, Teligen, and Contak Renewal TR. This waiver extended a previous waiver for all three devices until the earlier of either June 30, 2013, or one year after approval by the Food

implantable cardiac device for a limited time period, until December 31, 2013, at which time Boston Scientific expects that it will have completed the full enrollment in the ongoing clinical trial in which this device is being used. As set forth below, there is good cause for granting the requested waiver extension.

I. BACKGROUND

Boston Scientific is a leading worldwide manufacturer of implantable cardiac devices, such as pacemakers (or pacers), defibrillators, and cardiac resynchronization therapy ("CRT") devices. These devices are implanted into patients with cardiovascular disease and deliver electrical stimuli to treat abnormal heart rhythms. The "Cognis" product is a CRT device.[3] CRT devices are designed to resynchronize heart rhythms in patients suffering from heart failure. Most CRT devices, including the Cognis device, also include a defibrillation capability, which requires high voltage electronics, most notably high voltage capacitors.[4]

This implantable device uses inductive telemetry to communicate with heart monitoring and device-programming equipment, allowing physicians to download information stored in the device's memory to monitor a patient's cardiac events and the functioning of the implanted system. Inductive telemetry operates using magnetic coupling between a coil in a hand-held "wand" and a coil in the implanted device. A physician initiates a communication session with the implanted device by placing the wand on the patient's chest over the device to establish an inductive link, using the RF signals in the 90-110 kHz band, between the wand and the implanted

---

and Drug Administration ("FDA") of the replacement devices that will not operate in the 90-110 kHz band.

[3] The Cognis device is manufactured by Cardiac Pacemakers, Inc., an indirectly wholly-owned subsidiary of Boston Scientific.

[4] Such devices that include defibrillation are known as "CRT-D" devices.

device. The wand must be within centimeters of the device to detect the extremely low-power inductive transmissions from the Cognis device. The amount of time in which the Cognis device inductive system is emitting any RF signal at all typically is limited to just a few seconds per year, for this information-gathering session.[5] Furthermore, only the implanted device emits RF signals in the 90-110 kHz band; the programming and monitoring equipment transmits on a frequency outside this band.

The Commission's rules provide priority to the LORAN radionavigation system in this band, and this band is not available for unlicensed uses under Section 15.205 of the Commission's rules.[6] The Cognis device at issue here still is being manufactured, sold, and used, subject to the upcoming expiration of the waiver granted in the 2011 Waiver Modification Order. Boston Scientific has previously requested, and the Commission has previously granted, waivers to ensure that the life-enhancing benefits offered by this cardiac device remains available to patients who need them while the next-generation devices that do not emit in the 90-110 kHz band are made available.[7] As explained in Boston Scientific's 2011 Waiver Request,

---

[5] After authentication using the inductive system, the system switches over to a higher-speed communication in a different band at a much higher frequency.

[6] 47 C.F.R. § 2.106. The term LORAN refers to Long Range Aids to Navigation. LORAN-C operations ceased as of October 1, 2010.

[7] On June 6, 2006, Boston Scientific first requested a waiver of the Commission's rules with respect to the manufacture, sale, and use of three implantable cardiac devices (see *supra* note 2) that operate at 90-110 kHz, including the Cognis device, which at that time was approximately six years into a development cycle. With regard to the Cognis device, on November 16, 2006, the Commission issued an Order granting Boston Scientific a waiver to permit the manufacture, sale, and use of the Cognis device until November 16, 2009. *See* Waiver Order, ¶ 13. The Commission specified that devices implanted in patients under the provisions of the waiver will be permitted to continue to operate indefinitely. *See id*. note 16. The Commission determined that "the short-term product shortage that would result from taking the current devices off the market without a phase-out period would likely be detrimental to the public, and specifically medical patients and their families who benefit from their use." *See id*., ¶

the next-generation replacement devices for the Cognis device is part of the "Progeny" technology platform.[8] Following the Commission's grant of the 2011 Waiver Modification Order, Boston Scientific finished product development; completed a rigorous product development and testing process in order to ensure safety, efficacy, and reliability; and submitted

---

11. The Commission further concluded that there was a negligible chance that these products would interfere with LORAN-C operations at 90-110 kHz. *See id*.

When the Commission granted the waiver in 2006, the Cognis replacement product was still in development and not expected to receive FDA approval until 2008. On December 18, 2006, Boston Scientific requested a modification of the waiver for the Cognis device to provide sufficient time to bring the replacement product to market and to sell the Cognis device until a replacement product that does not employ the 90-110 kHz band could be developed and introduced. On July 11, 2007, the Commission modified the waiver to provide three years to market the Cognis device, commencing on the earlier of the date of FDA approval for the first device in the replacement series, or January 31, 2009. *See* Waiver Modification Order ¶ 14. Boston Scientific received FDA approval on May 8, 2008.

Despite a significant investment in quality and research and development, and due to unexpected delays in the product development process, Boston Scientific was required to request an extension of the waiver for the Cognis device. On May 5, 2010, Boston Scientific requested an extension of the waiver for the Cognis device until December 31, 2011, due to necessary but unplanned further design enhancements that arose during the final stages of development for the next generation device. The Commission granted that extension on September 15, 2010, recognizing that the waiver "present[s] 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," and that the extension granted would "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." *See* 2010 Waiver Modification Order, ¶ 10. In granting each of these waiver modifications, the Commission has recognized that "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." *See, e.g.*, *id.*, ¶ 10.

[8] *See 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*, Request for Further Extension of Waiver, ET Docket No. 05-331, at 3 (filed May 13, 2011) ("2011 Waiver Request"). "Progeny" was Boston Scientific's name for the development program. The commercial devices are known by other names. *See* 2011 Waiver Request, note 6.

its application for FDA approval.[9] Boston Scientific obtained FDA approval of the Cognis replacement device on November 17, 2011.[10] The current waiver thus is set to expire on November 17, 2012.[11]

While FDA approval of the Progeny products has cleared the path for the Cognis replacement devices to be brought to market, there remains one important reason to continue the manufacture, sale, and use of the Cognis device for a limited period of time: ongoing clinical trial that uses the Cognis device. In these unique circumstances, Boston Scientific seeks a limited further extension of the waiver previously granted for the Cognis device.

II. SPECIAL CIRCUMSTANCES EXIST WHICH JUSTIFY A LIMITED WAIVER EXTENSION

The Commission may waive its rules for good cause shown, where special circumstances warrant a deviation from the rule, and strict compliance with the rule would be inconsistent with

---

[9] Boston Scientific explained in its 2011 Waiver Request that the need for the further extension of its waiver for the three cardiac devices, including the Cognis device, was a result of the need to finish some product development work, the need for further FDA approval, and time to phase in the replacement devices. *See* 2011 Waiver Request at 6-10.

[10] Boston Scientific has similarly completed necessary product development and testing processes for the Teligen and Contak Renewal TR replacement devices; submitted its FDA applications for these replacement devices; and obtained FDA approval for the Teligen replacement device on November 17, 2011 and for the Contak Renewal TR replacement device on May 7, 2012. Boston Scientific is already phasing in the use of the Ingenio devices to replace the use of Contak Renewal TR devices and does not need an extension for the continued use of the Contak Renewal TR device. Boston Scientific is also phasing in replacements for the Cognis device and Teligen device. For the reasons noted further in this waiver request, Boston Scientific requests a waiver to continue use only of the Cognis device despite FDA approval of the Progeny product that is the replacement device for the Cognis device.

[11] The waiver was granted until the earlier of twelve months following FDA approval of the device or June 30, 2013. *See* 2011 Waiver Modification Order, ¶ 12.

the public interest.[12] The Commission, through its Office of Engineering and Technology ("OET"), previously found that permitting the continued manufacture, sale, and use of the Cognis device by Boston Scientific for the limited purpose described herein presented "an unusual and compelling public interest situation" justifying temporary waivers of Section 15.205 of the rules.[13] OET was willing to extend the current waiver until June 30, 2013.[14] In the instant petition, merely six months more is requested, until year-end 2013. The public interest justification is no less compelling now, when Boston Scientific is farther along toward the completion of its clinical trial, and has good reason to believe that full enrollment in its trial can be successfully completed in the requested time frame.

The Cognis device has been part of an ongoing clinical trial since 2010, in which Boston Scientific is collecting data related to patients' worsening heart failure. The Multisensor Chronic Evaluations in Ambulatory Heart Failure Patients ("MultiSENSE") clinical trial depends upon downloading of certain research software into the Cognis device after the device is implanted. This "conversion" into a research device may occur 30 or more days after the device is implanted. Importantly, the research software is not compatible with the Cognis replacement devices. Specifically, the replacement products are not configured to provide the necessary data and therefore the replacement products cannot be used for the clinical trial. Indeed, the value of

---

[12] 47 C.F.R. §1.3. *See generally Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990); *WAIT Radio v. FCC*, 418 F. 2d 1153, 1159 (D.C. Cir. 1969).

[13] 2011 Waiver Modification Order, ¶ 10.

[14] *See supra* note 10.

the work already completed by the clinical trial may be undermined if Boston Scientific cannot continue to sell the Cognis device for the limited purpose of completing the clinical trial.[15]

If the clinical trial cannot be fully enrolled, or if the results of a clinical trial are delayed by having to try to complete enrollment without new implants in the United States, then patients will potentially be denied the benefits of the planned technology designed to provide early detection of worsening heart failure. Similarly, the near-term potential for reducing economic burdens on Medicare may be lost, or delayed,[16] if physicians are denied the benefits of this important clinical information, specifically by better managing patients in order to avoid deterioration to decompensation that results in hospitalization.

Before the research of the MultiSENSE clinical trial can be completed, however, there are a number of steps that must occur, all of which are outside the control of Boston Scientific. Initially, a physician must implant the Cognis device in a patient. After the device is implanted the physician must identify patients who are eligible for the clinical trial based on having met certain enrollment criteria. Then a patient must agree to participate and become enrolled in the clinical trial.

At the time of its 2011 Waiver Request Boston Scientific expected the process of patient enrollment in the MultiSENSE clinical trial to move more quickly than it has, such that it expected full enrollment in the clinical trial to be completed before the most current waiver expired. As noted, the enrollment process is subject to factors outside Boston Scientific's control. However, based on the pace of enrollment over the past year, Boston Scientific

---

[15] The previously-collected clinical data is still useful, but the data is more useful if full enrollment is reached.

[16] Boston Scientific has previously noted that a "large fraction of heart failure patients receive Medicare benefits, which are paid with public tax dollars." 2011 Waiver Request, ¶ 10.

realistically expects that it will be able to complete the necessary enrollment in the second half of 2013,[17] such that the data from the clinical trial follow up can be gathered by the end of 2014.

A successful completion of the MultiSENSE clinical trial depends on the continued manufacture, sale, and use of the Cognis device for a short period of time, which will assure full enrollment in the clinical trial by qualifying patients with the implanted Cognis devices.[18] Boston Scientific seeks a limited further extension of the waiver previously granted for the Cognis device until the clinical trial enrollment can be completed. Boston Scientific expects that it can complete the MultiSENSE clinical trial enrollment by December 31, 2013, and therefore requests this limited further extension of approximately one year and one month. The currently scheduled expiration of the waiver for using the Cognis device – November 17, 2012 – will not be sufficient to complete full enrollment in the MultiSENSE clinical trial and produce information that will provide physicians with advance notice of their patients' worsening heart failure and allow for earlier medical intervention. As Boston Scientific stressed in its 2011 Waiver request, "[e]arly intervention benefits both the patient, who enjoys better health, and the public, which does not bear the cost of hospitalization of the patient."[19]

---

[17] Boston Scientific is earnestly working to complete enrollment in the clinical trial as soon as possible, including enrolling patients from medical centers in Europe. Nonetheless, even with these European enrollments the process is still slow and the inclusion of European participants has not been sufficient to complete full enrollment in the clinical trial by the waiver expiration date.

[18] Boston Scientific expects to sell just a few hundred Cognis devices after November 2012. The full enrollment for the clinical trial would comprise a total of 900 patients.

[19] 2011 Waiver Request at 10.

III. THE PUBLIC INTEREST WILL BE SERVED BY EXTENDING THE WAIVER, AND STRICT COMPLIANCE WITH THE RULE WOULD BE INCONSISTENT WITH THE PUBLIC INTEREST

Granting Boston Scientific's request for a limited further extension of the waiver period for the Cognis device in order to complete the MultiSENSE clinical trial will serve the public interest. The Commission recognized the importance of Boston Scientific's cardiac devices to heart patients in the Order that initially granted relief to Boston Scientific, and throughout this proceeding.[20] The MultiSENSE clinical trial is expected to deliver a number of important results, including:

- providing data about patient events during worsening heart failure;
- demonstrating how sensor measurements vary during patient daily activities and during the development and recovery from events of worsening heart failure;
- aiding in the development of algorithms capable of detecting the onset of worsening heart failure prior to the overt presentation of patient symptoms, using reference measurements – specifically thoracic impedance, heart sounds, and physiologic responses to activities and respiration.

Boston Scientific expects that this data will potentially lead to the development of technology designed to detecting worsening heart failure and that, with advance notice, it will provide patients and physicians with the ability for earlier medical intervention, saving patient lives and reducing economic burdens of public health costs.

---

[20] Waiver Order ¶ 11; *see also* 2011 Waiver Modification Order, ¶ 10 and 2010 Waiver Modification Order, ¶ 10, *citing* Contak Renewal TR Waiver Modification Order, ¶ 11 ("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") (footnote omitted).

The compelling public interest benefits that are presented by the continued use of the Cognis device are a matter of record. In the 2011 Waiver Modification Order and in prior orders, relief from the rule was granted because of the strong evidence that critical medical benefits would be realized by permitting these devices to remain in use for a short time longer, and enforcement of the rule would not serve the public interest. Indeed, OET found that these devices present "an extremely small risk of harmful interference to other authorized operations" in the 90-110 kHz band.[21] As Boston Scientific noted previously, the company is not aware of any interference complaints related to any of its cardiac implant devices that operate at 90-110 kHz.[22] Moreover, the limited emissions that occur in a controlled clinical environment for only a few seconds at a time serve to minimize the chance of an interference problem.[23]

Boston Scientific urges OET once more to find that the public health benefits, including the ultimate life-enhancing benefits for patients, that are expected to be derived from allowing continued use of the Cognis device in the MultiSENSE clinical trial far outweigh any benefit that could be derived from enforcing the rule and denying the requested waiver. Good cause exists

---

[21] 2011 Waiver Modification Order, ¶ 10. *See also id.* ("Given the remote likelihood of such interference, . . . grant of this waiver will not contravene the underlying purpose of Section 15.205 of the Rules").

[22] 2011 Waiver Request at 12. Notably too, "[t]here have been no reported cases of interference. LORAN-C users include the U.S. Coast Guard and non-federal aviation and Private Land Mobile services, and LORAN-C receivers thus typically operate on mobile air, land and marine platforms. It is extremely unlikely that a cardiac device communicating in the restricted band with nearby external clinical equipment would interfere with any LORAN-C communications." 2011 Waiver Request at note 23.

[23] The Commission has consistently acknowledged that the risk of interference with LORAN-C operations in the restricted 90-110 kHz band is negligible. Waiver Order ¶ 11; Contak Renewal TR Waiver Modification Order ¶ 11; 2010 Waiver Modification Order ¶ 10. LORAN-C operations ceased as of October 1, 2010. Coast Guard, Terminate Long Range Aids

for extending the waiver beyond the current November 17, 2012 expiration until December 31, 2013.

Moreover, respectful of the Commission's rules and the limited relief previously granted, Boston Scientific has been diligent in pursuing alternatives and hastening the transition to fully compliant devices. While Boston Scientific has completed the necessary steps to transition from use of the three of the cardiac implant devices that have been the subject of previous waiver requests to the replacement devices that do not use RF signals in the 90-110 kHz band, the successful completion of the MultiSENSE clinical trial warrants a limited further extension of the waiver for continued use of the Cognis device, and the low-level emissions in the 90-110 kHz band, for the duration of the MultiSENSE clinical trial.

There is ample cause to grant the requested extension. The public interest benefits of completing the MultiSENSE clinical trial are significant. The delays in completing full enrollment in this clinical trial have been beyond the control of Boston Scientific. Yet, Boston Scientific realistically expects that full enrollment in the clinical trial can be successfully completed by December 31, 2013.

IV. CONCLUSION

For these reasons, Boston Scientific requests a limited further extension of the waiver to allow it to manufacture, sell, and use the Cognis device until December 31, 2013, when it expects to complete full enrollment in the MultiSENSE clinical trial enrollment. This further extension request is limited to the length of time required to complete the MultiSENSE clinical trial enrollment using the Cognis device. The extension will provide the opportunity for life-enhancing benefits from information derived from the clinical trial, while imposing at most a

---

to Navigation (Loran-C) Signal, Notice, Docket No. USCG-2009-0299, 75 Fed. Reg. 998 (Jan. 7, 2010).

negligible interference potential to other users of this 90-110 kHz band. The requested extension is for a limited period of time and for a limited purpose.

Respectfully submitted,

/s/
Karen Brinkmann
Robin Tuttle
KAREN BRINKMANN PLLC
555 Eleventh Street, NW
Mail Station 07
Washington, D.C. 20004-1304
(202) 365-0325
KB@KarenBrinkmann.com

Counsel for Boston Scientific Corporation

August 8, 2012

|||