# mHealth Alert: FCC Extends Boston Scientific's Authority for Implanted Cardiac Devices

7/20/2009

The Federal Communications Commission (FCC) recently granted a rule waiver requested by Boston Scientific Corporation (Boston Scientific), allowing it to continue to manufacture and market its Contak Renewal TR product line of implanted cardiac medical devices. The rule waiver remains valid until May 8, 2011 or 90 days after the date on which the Food and Drug Administration (FDA) approves Boston Scientific's replacement for the Contak Renewal TR devices (the Cognis CRT-P product line), whichever comes earlier.

Boston Scientific manufactures several lines of implantable cardiac medical devices. Certain of these devices operate in bands (the 90-110 kHz band) not normally permitted for unlicensed, low-power communications devices. Boston Scientific is developing its next generation of implantable devices, which will use frequencies that are available for lower power, unlicensed wireless use. In order to permit Boston Scientific to use the restricted frequency band while it develops its next–generation technology, the FCC issued Orders in 2006 and 2007, waiving its rules so that Boston Scientific could continue to manufacture and sell the non-compliant devices. In particular, the 2006 Order gave Boston Scientific three years to continue to manufacture and market, among others, the Contak Renewal products, while the 2007 Order allowed Boston Scientific to manufacture and market the Cognis and Teligen series of devices (more advanced than the Contak Renewal line, but still not FCC-compliant) for three years after FDA approval of those devices. The FDA approved the use of the Cognis and Teligen devices on May 8, 2008, meaning that the FCC's waiver for those devices is scheduled to expire on May 8, 2011.

Because the three-year waiver issued in 2006 for the Contak Renewal product is scheduled to expire in November, Boston Scientific asked that the FCC extend the waiver for that product until the terminal date of the 2007 waiver (May 8, 2011) or 90 days from the time the FDA approves the replacement for the Contak Renewal TR product, whichever is earlier. In support of its request to extend the current waiver, Boston Scientific showed that it is working on the FCC–compliant Cognis CRT-P (the replacement for the non-compliant Contak Renewal), but that development is proceeding slower than it anticipated.

The FCC found that while product delays alone generally do not merit regulatory relief, the benefits provided by the Contak Renewal devices did support granting the requested relief. It also found that Boston Scientific is attempting to transition to the compliant Cognis CRT-P devices rather than interim, non-compliant devices. Based on those efforts and the lack of likely interference to other devices, the FCC extended the waiver for the Contak Renewal devices, at the latest, to the date when the waiver for the Cognis and Teligen devices expires—May 8, 2011.

*For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.*

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