Boston Scientific

Date: November 8, 2011

Subject: FCC Cover Letter

Introduction

The Model 6498 (also known as the Wave) LATITUDE™ Communicator is a new product for the Guidant Corporation (a wholly owned subsidiary of Boston Scientific Corporation doing business as Boston Scientific Cardiac Rhythm Management, hereinafter referred to as BSC). This is the fourth device intended for home monitoring of BSC implantable cardiac rhythm devices. This is a new product and will therefore be an original certification.

BSC is seeking a system approval of the Model 6498 LATITUDE™ Communicator which includes a transceiver subsystem operating at 916.5 MHz that is used to communicate with BSC implantable devices and an embedded pre-certified cellular module (Sierra Wireless SL6087 - FCC ID: N7NSL6087) to upload data collected from the patient's device to a Boston Scientific data server. The FCC ID chosen for this product is based on previously similar products and is ESCCRM649812. The FCC rules applicable to this product for the 916.5 MHz radio per this submission include CFR FCC Part 15.249, Part 15.207, 15.109, and 15.107. Additionally, CFR FCC Part 22H and Part 24E are applicable due to the integration of the pre-certified cellular module. Since the product also includes an analog modem connection, FCC Part 68 also applies.

Device Description

The Wave Communicator is an externally powered medical device that communicates with BSC radio frequency (RF) enabled implantable devices via a 916.5 MHz RF link. The retrieved implantable device data along with Communicator status information is transmitted back to a central database. The data can then be accessed by a health care professional on a Boston Scientific secure website.

A custom BSC communicator software application is run on an embedded microprocessor that controls all of the communicator's features/functions. The 916.5 MHz RF transceiver configuration and mode of operation is controlled via the on board processor. The transceiver is co-located with a pre-certified cellular module that enables collected data to be sent to a Boston Scientific data server. Although the radios are co-located, the software application will only activate one radio at a time, i.e. when one radio is active, the other radio is powered off.

Figure 1 shows the Wave Communicator. The high level assembly includes one printed circuit assembly which contains all of the device circuitry and an embedded antenna to support both radios. The software application switches the antenna to the correct radio based on the device mode of operation. The communicator also includes a user interface, comprised of a combination of LED indicators and switches/buttons that provide device

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setup, feedback of the communicator's status, and the ability to perform an unscheduled implanted device interrogation. USB ports (2) are provided for future extensibility (Bluetooth/Ethernet dongles, external memory, etc.) of the communicator. The device is wall-powered using an AC/DC power brick and is approximately the size of an alarm clock.

Figure 1. BSC Model 6498 Communicator