Date: 12/29/2014

Re: Model 6290 Latitude™ Communicator: FCC Cover Letter

The Guidant Corporation (a wholly owned subsidiary of Boston Scientific Corporation doing business as Boston Scientific Cardiac Rhythm Management) Model 6290 LATITUDE™ Communicator is an in-home patient monitor. The Model 6290 Communicator provides radio frequency (RF) telemetry in the 402 – 405 MHz MedRadio band for use with radio frequency (RF) enabled BSC implantable cardiac rhythm management devices.

Introduction

The Model 6290 LATITUDE™ Communicator is an existing product for the Guidant Corporation. The Model 6290 Communicator provides radio frequency (RF) telemetry at 402 – 405 MHz for communication with RF enabled BSC implantable cardiac rhythm management devices. The original device firmware is being updated to add support for the BSC Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) device. The existing Model 6290 functionality with other BSC devices remains unchanged.

The Model 6290 was originally authorized under FCC ID ESCCRM629013. This authorization request is per the Class II Permissive Change process to include the radio updates required to support the added S-ICD device functionality.

The Model 6290 Communicator is paired to a patient's implantable device based on information it receives from the Boston Scientific LATITUDE™ server during setup. The Communicator downloads information which identifies the patient's implantable device type. The Model 6290 firmware uses the appropriate MedRadio band telemetry per the existing authorization or the updated S-ICD telemetry scheme.

The FCC rules applicable to this product include CFR FCC Part 95I, Part 2.1046, Part 2.1091, Part 15.107, and Part 15.109. The product includes an analog modem connection; therefore FCC Part 68 also applies.

Device Description

The Model 6290 LATITUDE™ Communicator is an externally powered medical device that communicates with BSC radio frequency (RF) enabled implantable devices via a 402 - 405 MHz RF telemetry 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 from a Boston Scientific secure server.

A custom BSC communicator software application is run on the device embedded microprocessor which controls all of the communicator's features/functions. The RF transceiver configuration and mode of operation is controlled via this processor.

Figure 1 shows the Model 6290 LATITUDE™ Communicator. The high level assembly includes one printed circuit assembly which contains all of the device circuitry and an embedded antenna. The software application enables the transceiver when required for telemetry. The communicator also includes a user interface, comprised of a combination of LED indicators and switches/buttons that provide device setup, feedback of the communicator's status, and the ability to perform unscheduled implanted device interrogation. Two (2) USB ports are provided for extensibility (Bluetooth/Ethernet dongles, external memory, etc.) of the communicator. The device is wall-powered using an AC/DC power adapter.

Figure 1 BSC Model 6290 LATITUDE™ Communicator