

Date: 7/31/2014

Re: Model 3200 Emblem S-ICD Programmer: FCC Cover Letter

The Guidant Corporation (a wholly owned subsidiary of Boston Scientific Corporation doing business as Boston Scientific Cardiac Rhythm Management) Model 3200 Emblem S-ICD Programmer is a component of the Cameron Health/Boston Scientific S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. The programmer communicates wirelessly in the MICS (402-405 MHz) frequency band with the implanted S-ICD device to enable adjustment of programmable settings and data collection during implantation procedures and device/patient follow-up exams.

Introduction

The Model 3200 Programmer is a second generation product for the Guidant Corporation. The Model 3200 Programmer provides radio frequency (RF) telemetry in the 402 – 405 MHz MICS band for communication with RF enabled S-ICD devices. The first generation device is approved under FCC ID SDYCHI2020. This authorization request for the Model 3200 Programmer is a result of a device firmware update which will add a second telemetry channel. This will be an original certification.

BSC is seeking approval of the Model 3200 Programmer which includes a transceiver subsystem operating at 402 - 405 MHz for communication with S-ICD devices. The FCC ID chosen for this product is ESCCRM320014. 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 Model 3200 Programmer also includes a Bluetooth radio authorized under the limited modular approval of ESCCRM70514. As part of the new authorization the Grantee Code is transitioning from Cameron Health Inc. (SDY) to Boston Scientific Corporation (ESC).

Device Description

The Model 3200 Programmer is an externally powered medical device that communicates with BSC S-ICD enabled implantable devices via a 402 - 405 MHz RF telemetry link. The programmer is operated by a healthcare professional or a Boston



Scientific employee during S-ICD implantations or device/patient follow-up exams. During operation, the programmer displays device and patient data collected through the wireless telemetry link and allows programming of implanted device parameters. The Model 3200 Programmer embedded Bluetooth module can be used to send reports to a paired Bluetooth printer for storage/review.

The Model 3200 Programmer consists of a commercial tablet computer connected to a proprietary RF printed circuit assembly known as the Programmer Radio Board (PRB). The tablet computer and PRB are placed in a common mechanical housing. The Model 3200 Programmer antenna, “Telemetry Wand”, is attached to the PRB through an RF connector that is accessible from outside of the programmer housing. The Telemetry Wand (Model 3203) includes an integrated 3 meter cable to allow the user to place the antenna for optimal performance.

A custom BSC programmer software application is run on the Model 3200 embedded tablet processor. The application controls all of the programmer’s features and functions. The PRB contains a Field Programmable Gate Array (FPGA) that includes the interface logic between the tablet processor and the RF transceiver circuitry.