SUMMARY OF:

P110042/S09
Model 3200 Q-TECH Programmer

Cameron Health, Inc.
905 Calle Amanecer, Suite 300
San Clemente, CA 92673

BACKGROUND/REASON FOR SUPPLEMENT

The subject 180 Day PMA/S was received on June 10, 2013, by the Cameron Health Inc., a subsidiary of Boston Scientific, is requesting approval for a new Programmer, Model 3200, to support the approved S-ICD® System. The Model 3200 Programmer is a modified commercially available Samsung Galaxy 2 7.0" tablet. The manufacturing required to accomplish the modifications will occur at the (b)(4) 3rd Party CCI manufacturing facility located in (b)(4) 3rd Party CCI

The Model 3200 Q-TECH Programmer is functionally equivalent to the current market approved the Model 2020 Q-TECH Programmer, which was included in the original PMA P110042. There are no changes in the therapy, nor are there any new features introduced, nor features removed from the Model 2020 Q-TECH Programmer.

There were no changes required to the Pulse Generator Firmware to accommodate the Model 3200 Programmer. Few minor modifications for the software User Interface of the 3200 Programmer, such as the size of the screen required changes due to the hardware differences between the 3200 Programmer vs. the Model 2020 Programmer.

INDICATIONS FOR USE

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S.

DEVICE DESCRIPTIONS

The Model 3200 Q-TECH Programmer (The subject device), is a component of the Cameron Health S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. The programmer communicates wirelessly with the SQ-RX device to enable adjustment of programmable settings and data collection via the Telemetry Wand.

DEVICE TESTING/REVIEW

A Ripple Effects Analysis was conducted to analyze changes between the Model 2020 Programmer and the subject Model 3200 Programmer. This information is used to assess the appropriate verification and validation effort for each change. The Model 3200 Programmer introduces new programmer hardware and software implementation which, from a system perspective, is functionally equivalent to the Model 2020 Programmer. Consequently, changes will be limited to implementation details while the system requirements and clinical validation will remain unchanged.

The analysis at the system level included a determination of the impact of each change on manufacturing, clinical studies, labeling, and systems engineering activities. The analysis at the subsystem level included a determination of the impact of each change on the requirement and design specifications, and to determine the optimal approach to verification and validation Testing.

The company conducted the following tests and based on the pass results, this is acceptable. Those tests are:

Electromagnetic Compatibility (EMC) / Electrical Safety;
Electrostatic Discharge ;
Telemetry;
Medical Implant Communications Service (MICS) for the S-ICD System;
Mechanical Design; and
Packaging and Environmental Design Verification.

Design verification testing (DVT) of the Programmer Software Application was conducted for the Model 3200 Programmer with the version 2.00.03 software has some minor software anomalies. The company claims that, those minor software anomalies do not affect the safety of the implanted patient, therefore, it is acceptable.

In addition, the company conducted the Design validation testing, to demonstrate that the S-ICD System continues conform to user needs and intended use with the Model 3200 Programmer. Design validation testing included: System Design Analysis Tests and Simulated Use Tests. All testing passed. Based on the information in the file, it shows all the tests are passed, this is acceptable.

Based on the risk management report for the Model 3200 Programmer contains two components that are considered high integrity: the power supply and the battery. However, as stated in the Programmer Hardware Requirements Specification the power supply is IEC 60601-1:2005 certified, and the battery is IEC 62133 certified. Therefore, this is acceptable.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The company provided the labeling for the Model 3200 Programmer in the subject file. Based on the information in the file, this is acceptable.

CONCLUSION

.Based on the information in the subject file, I recommend the approval of the subject device. Please note, the software issues associated to other languages (not English) are acceptable for the subject file.