SUMMARY OF: P890003/S260

EC/ECL ECG CABLE AND LEAD WIRES; 128743 ECG PLUS / MEDTRONIC, INC.

EXECUTIVE SUMMARY/BACKGROUND

Medtronic is seeking approval for manufacturing, design, packaging, and labeling changes for the ECG cables, lead wires, and ECG plug referenced above.

Medtronic is securing a new contract manufacturer of the ECG cables, lead wires, and ECG plug. As a result, multiple design changes and assembly specification changes were included for these components. These changes included material, dimensional, component replacement, and revision of the clip contact. Changes were also made to the labeling and the incoming inspection procedure at Medtronic.

There were multiple interactive interactions with Medtronic to resolve questions related to the submission.

DESCRIPTION OF CHANGES/ REASON FOR SUPPLEMENT

Currently (b)(4) Trade Secret/CCI manufactures the Medtronic 2090EC and 2090ECL ECG cable and lead wires and ECG plug. (b)(4) Trade Secret/CCI In the future, the ECG Cable Assembly will be manufactured to Medtronic requirements, by (b)(4) Trade Secret/CCI The (b)(4) TS/CCI manufacturing operations use processes that meet Medtronic requirements for qualified processes, product traceability, in-process and final quality inspections for process steps and final functional testing.

In order to accommodate the new manufacturing processes at (b)(4) TS/CCI subsequent changes to product design were also required. The design changes consist of material changes, dimensional changes, component replacements and revised design of clip contact. These changes were made to reduce costs and streamline the manufacturing process at (b)(4) TS/CCI

In addition to the changes described above, changes were also made to the incoming inspection procedure at Medtronic as well as to the product labeling. The incoming inspection procedure was updated to incorporate the new requirements of the design specification. The labeling was updated to include country of origin information and to update symbols to ensure compliance to international requirements.

INDICATIONS FOR USE

The Model 2090EC/ECL ECG cable and lead wires connect the programmer to skin electrodes for ECG and measurement functions requiring surface detection of cardiac and implantable device signals.

DEVICE DESCRIPTION

The Medtronic Model 2090EC/ECL ECG cable and lead wires connect five skin electrodes to either the Medtronic CareLink Programmer, Model 2090, or the Medtronic Model 9790/C Programmer. The Model 2090EC is approximately 2.6 m (103 in.) in length, and the Model 2090ECL is approximately 5.5 m (215 in.) in length.

The cable and lead wires are reusable and supplied non-sterile. The cable and lead wires can be sterilized if necessary.

The 2090EC/ECL ECG Cable and Lead Wires and 128743 ECG Plug ("cable assembly"), were approved by FDA as accessories to the 2090 Programmer under PMA P890003/S065 March 13, 2002.

RISK ANALYSIS

The firm performed a risk management analysis to mitigate design hazards from assembly and component perspective as a result of the change in component manufacturer. A Design Failure Modes Effect Analysis was created to identify risk occurrence and severity associated with various aspects of the cable assembly and components. All design changes were reviewed and the results of the risk management activities were documented.

The Risk Analysis was reviewed and this information appears to be adequate. The risk levels were found acceptable after the appropriate mitigations.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS

The firm conducted cytotoxicity, sensitization, irritation, and systemic toxicity (acute) testing to demonstrate that the proposed material changes did not impact the biocompatibility of the device.

A Major Deficiency letter was sent to the firm requesting the full test reports for the biocompatibility tests.

In A001, the firm provided the requested full test reports. The full test reports were reviewed and appeared to be adequate. The testing supported the conclusion that the material changes would not be expected to impact the biocompatibility of the subject device.

ELECTRICAL SAFETY/EMC

The sponsor conducted Electrical Safety testing to demonstrate that the modifications to the component design did not impact the component's ability to meet the Electrical Safety requirements. The testing performed included cleaning, humidity pre-conditioning, continuity, insulation resistance, and environmental. The sponsor also conducted EMC testing to demonstrate that the modifications to the component design did not impact the component's ability to meet the EMC requirements. The testing performed included pre-visual inspection, EtO sterilization, narrow band radiated emissions, conducted RF immunity, and ESD immunity.

A Major Deficiency letter was sent to the firm and included a request for the full test report for the EMC test.

In A001, the firm provided the requested full EMC test reports. The Electrical Safety and full EMC test reports were reviewed and appeared to be adequate. The testing supported the conclusion that the component design changes would not be expected to impact the components ability to meet Electrical Safety and EMC requirements.

BENCH TESTING

The sponsor conducted a qualification of the components manufactured by the new supplier. This qualification covered multiple areas include conformance to standards, lead assembly tests, trunk cable tests, and shorting plug tests. Standards testing included lead resistance, sink current, flex life, tensile strength, mate/unmate, contact resistance, connector retention force, and triboelectric noise. Lead assembly tests included continuity, insulation resistance, environmental, cleaning, and shock. Trunk cable tests included environmental, cable continuity, cable length, and label. Shorting plug tests included dielectric strength and drop test.

The sponsor also conducted a validation of the component assembly. This validation included a visual inspection of the assembly and a Patient Simulator Test that validated the ability of the cable assembly to transmit ECG signals from the patient to the programmer.

Finally, the sponsor conducted a transfer test to verify that the changes made to the component assembly meet the part specifications, programmer specifications, and standard requirements. Testing performed included pre-test visual inspection, EtO sterilization, input impedance, defibrillation withstand, noise (cable, circuit, and output display), channel crosstalk, cleaning and disinfection, and dielectric withstand voltage.

The qualification, validation, and transfer test reports were reviewed and appeared to be adequate. The testing demonstrated that the new component assembly manufactured by the new supplier was qualified and validated for its intended use.

STERILIZATION

The firm stated that, while the component assembly is sold non-sterile, the component assembly is intended for re-use and the manual includes directions for EtO sterilization. Therefore, the firm conducted a sterilization validation to demonstrate that the components continued to meet acceptable sterility levels, acceptable EtO residual levels, and that the product can withstand multiple sterilization cycles.

A consult was issued to a sterility reviewer for a review of the modifications to the end-user sterilization instructions. The consultant identified that insufficient information existed for the end-user to successfully perform re-sterilization of the component assembly.

A Major Deficiency letter was sent to the firm and included requests for the number of total sterilization cycles for the components, that the residual data be presented in different units, clarification on the sterile barrier system, and modifications to the end-user sterilization instructions in the user manual.

In A001, the sponsor provided clarification on the total number of cycles, the residual data in the units required, clarification on the sterile barrier system, and revised the end-user sterilization instructions in the user manual. This information was reviewed and appeared to be adequate. The sterilization testing demonstrated that the components continued to meet acceptable sterility levels, acceptable EtO residual levels, and that the product could withstand multiple sterilization cycles.

LABELING

The firm stated that the only changes to the labeling were the Country of Origin and new part numbers. This information was reviewed and appeared to be adequate.

MANUFACTURING

Manufacturing information was submitted in this submission related to the new supplier of the component assembly. The Office of Compliance was consulted to determine if the component assembly would be considered a "finished device" and whether the change in component manufacturer would be considered a Site Change. The Office of Compliance determined that the component assembly was a finished device and that a review of the Site Change manufacturing information was required. A separate review of the manufacturing information was conducted by the Office of Compliance and was not reviewed by ODE. As part of their review, the Office of Compliance initiated an inspection of the component manufacturer. The inspection report was reviewed by the Office of Compliance and was found to be acceptable. The Office of Compliance recommended this change be approved.

NOT APPLICABLE

The following review areas were not applicable given the change requested. The components do not contain software. Further, the impact of the change proposed can be sufficiently evaluated with bench testing; therefore, animal and clinical data are not necessary.

SOFTWARE
ANIMAL STUDIES
CLINICAL DATA
PACKAGING/SHELF LIFE

CONCLUSION

The firm has provided sufficient evidence to support their request for approval for the manufacturing, design, packaging, and labeling changes for the ECG cables, lead wires, and ECG plug. As demonstrated by the firm's testing, these changes are not expected to impact the design and performance specifications for the components. The information provided supports a recommendation of approval for the subject PMA/S.