DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

DATE: November 15, 2010

TO: The Record

THRU: Mitchell Shein
Chief, PDLB/DCD/ODE/CDRH

Initials Date

FROM: James Lee

SUBJECT: P980035/S150; Adapta, Versa, Sensia and Relia lmplantable Pulse Generators (IPGs); Medtronic Inc.

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BACKGROUND/REASON FOR SUPPLEMENT

PMA/S Amendment 01 was submitted dated November 4, 2010. The amendment is to request the exception from the CDRH/OC warning later issued on November 9, 2009. This amendment was reviewed and accepted by CDRH/OC. The acceptance e-mail from the CDRH/OC was included as part of this file for the documentation.

The changes for the subject file are:

Change 1:
Medtronic's PWB supplier (b) (4) is unable to provide Medtronic with long-term supply of components. Medtronic is seeking approval for an alternate supplier to ensure continued availability of the components.

Change 2:
In order to improve manufacturability, the minor layout changes and addition of fiducials are being made.

Change 3:
A change to the used in the of the to improve substrate processing and provide better adhesion of epoxies.

Change 4:
Specification changes are being made for clarification and to correct the latest documentation errors.

Note: The company claims, none of the above changes are the result of the field performance issue.

REVIEW ETEAM

Jay Jariwala (FDA/CDRH/OC/DOEB/CREDB) has conducted a consult review regarding the manufacturing information. The manufacturing information has been determined to be acceptable. The consult number of the CTS is CON0914373. The original consult review memo. is placed in the file for the documentation.

CDRH/OC Branch Chief J. Simms accepted the information in the PMA/S Amendment 01, and his acceptance e-mail dated November 5, 2010, is placed in the file for the documentation.

INDICATIONS FOR USE

NOTE: The "indications for use" are unaffected by the purposed changes in this application and are as follows for all models of the Medtronic Adapta/Versa/Sensia/ Relia implantable pulse generators:

> The Medtronic Adapta/Versa/Sensia/Relia implantable pulse generators (IPGs) are indicated for use in patients who may benefit from rate responsive pacing to support cardiac output during varying levels of activity. These devices are indicated for use in patients who have experienced one or more of the following conditions:
>
> - symptomatic paroxysmal or permanent second- or third-degree AV block;
> - symptomatic bilateral bundle branch block;
> - symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders;
> - bradycardia-tachycardia syndrome;

- vasovagal syndromes or hypersensitive carotid sinus syndromes.

These devices are also indicated for use in patients who may benefit from maintenance of AV synchrony through the use of dual chamber modes and atrial tracking modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony. Dual chamber modes are indicated for use in patients who have experienced one or both of the following conditions:

- various degrees of AV block;

- VVI intolerance (for example, pacemaker syndrome) in the presence of a persistent sinus Rhythm.

This device is also indicated for VDD pacing in patients who have adequate rates and one or both of the following conditions.

- A requirement for ventricular pacing when adequate atrial rates and adequate intracavitary atrial complexes are present. This includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit or when pacemaker syndrome had existed or is anticipated.

- A requirement for intermittent ventricular pacing despite a normal sinus rhythm and normal AV conduction.

DEVICE DESCRIPTION

Change 1:
Due to the advances of the IC industry, the isolated coating for the surface layers (top and bottom, layer #1 for the top, and layer #x for the bottom) of the Printed Wiring Board (PWB) will be changed from (b) (4) to (b) (4). Attachment 10 of the subject file contains the information of the coating materials with the test results. The test reports indicate the passe of the tests, and this change is acceptable to be used as the hybrid board of the device (IPG).

Change 2:
The company claims, the layout changes were made to improve manufacturability, to (b) (4). Also, some additional fiducials were added to improve manufacturability. A fiducial is a special geometric shape placed on the copper layer, which is recognized by the assembly equipment and used to guarantee/adjust the X and Y position of the PWB as it flows thru the assembly line. This change is for the manufacture process of the hybrid board in the device (IPG). The change and the validation tests are acceptable.

Change 3:
The design will be changed to a design for the of the IPG hybrid. The tests for this change are passed.

Change 4:
The specification changes are being made for clarification and to correct some documentation errors. Those changes were verified again with the company as part of the inter-active review process.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS

N/A

ANIMAL STUDIES

N/A

ELECTRICAL and MECHANICAL SAFETY

The company conducted a number of the tests to verify that all the changes are acceptable for the IPG.

Those test sets are the verification tests, qualification tests, and device level testing; the test reports are located in various attachments of the file. The following are the test cases:

The verification tests are:

- Design Reliability Assessment Verification of the (b) (4)
- Low Power Design (QBS-025596).

The qualification tests are:

- Qualification of (b) (4) on the (b) (4) (ETR 021944);
- Qualification of (b) (4) (QBS-024382);

- PWB to Assembly Processes Operational Qualification by Equivalence Report (PQR-025690); and

- Qualification of (CQP-024312)/Qualification of – (CQR-025256).

The device level testing:

- Interim Electrical Evaluation (baseline);
- Magnetic Field Interference;
- Electrosurgery;
- Monophasic Transthoracic Defibrillation;
- Biphasic Transthoracic Defibrillation;
- X-ray Test;
- Temporary Response during Exposure to Continuous Wave (CW) Sources;
- Behavior during Application of Modulated Interference from

- Temperature Test;
- Mechanical Vibration;
- Mechanical Shock;
- Controlled Free Fall Drop;
- Cyclic Shield Deflection test;
- Device Functional Tests;
- Destructive Analysis Test;
- Barometric Pressure test;
- Device Functional Tests; and
- Interim Electrical Evaluation (with purposed changes).

The company claims, all the tests are passed, therefore, the testing information is acceptable for the purposed changes.

SOFTWARE

N/A

CLINICAL DATA

N/A

SUMMARY OF INTERACTIVE REVIEW/CORRESPONDENCE

On February 1, 2010, the company clarified, all the L368 IC changes referred in the subject file were approved by FDA as part of P980035/S140 (September 2009), the subject file contains the additional changes, and all the changes will be implemented after the approval

of this file (P980035/S150). The exchanged e-mails between the FDA and the company are placed in this file for the documentation.

On February 17, 2010, the company clarified, all the remainder issues of this file. This includes the testing process as well.

CONCLUSION

Based on the information in the file, the company has provided appropriate data to demonstrate that devices modified as purposed are safe and effective.

RECOMMENDATION – I recommend that the supplement be approved, based on the CDRH/OC accepted the information in the PMA/S A01.

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James Lee **Date**
Reviewer

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Mitchell Shein **Date**
Chief, PDLB