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: June 4, 2010

TO: The Record

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

Initials Date

FROM:

SUBJECT: P980035/S153 and P980035/S153/A01
Manufacturing and Design change to XC202 Ceramic Capacitor

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BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Medtronic (the company) dated December 15, 2009, requesting approval for the manufacturing and design changes to XC202 Ceramic Capacitor. The subject file is to correct the known field issues with respect to the XC202 ceramic Capacitor. FDA letter dated April 29, 2010, was send to the company requesting additional information. The company provided the additional information to FDA via. PMA/S Amendment 1 dated May 28, 2010.

The following PG Models are impacted by the subject file:

EnRhythm Model P1501DR; Adapta IPG (DR/SR/VDD) Models ADD01, ADDR01, ADDR03, ADDR06, ADDRL1; Versa DR IPG Model VEDR01; Sensia

IPG (D/DR/S/SR) SED01, SEDRL1, SES01, SEDR01, SESR01; and Relia IPG (D/DR/S/SR/VDD) Models RED01, REDR01, RES01,RESR01,REVDD01.

The Adapta, Versa, and Sensia Implantable Pulse Generator models were first approved under P980035/S043 on July 17, 2006. They were later revised under P980035/S073 on May 13, 2008 to be built with the MA07435A Hybrid subassembly. This change impacts models built with the MA077435A hybrid, the nEw3 platform.

The Relia Implantable Pulse Generator models were approved under P980035/S097 on November 26, 2008. These models are also built with the MA077435A hybrid, the nEw3 platform.

EnRhythm Implantable Pulse Generator was approved under P980035/S38 on April 28, 2005. These models are built with the 180964 Hybrid.

REVIEW TEAM

CDRH/OC/DOEB/CREB, conducted the consult review with respect to the CDRH/OC issues. This includes the manufacture information, QSR, and the post market reported field issues. consult review memo. (dated: April 5, 2010) indicates that, CDRH/OC accepts the manufacture information in the subject file, and will follow-up the field reported issues within the CDRH/OC, not as part of the subject file.

INDICATIONS FOR USE

NOTE: The "indications for use" are unaffected by the purposed changes in this PMA/S, and are as follows:

Adapta, Versa, Sensia, and Relia Indications For Use

The 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.

EnRhythm Indications For Use

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity;

- Accepted patient conditions warranting chronic cardiac pacing include:

    - 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 to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias.

The device is also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output;
- VVI intolerance (for example, pacemaker syndrome) in the presence of persistent Sinus rhythm.

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.
Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in bradycardia patients with atrial septal lead placement and one or more of the above pacing indications.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS: N/A

ANIMAL STUDIES: N/A

COMPONENT TESTING

The company conducted a number of the tests to verify XC202. Those test sets are part of the XC202 qualification testing in Attachment 1 of the PMA/S submittal, the qualification report of XC202 Multilayer Ceramic Capacitor, .
Those are:

- **Initial Electrical and Dimensions**
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)

- **Performance/Stress Tests**
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
    - (b) (4)

Dielectric Aging (Attachment 1 of the PMA/S submittal)

In addition, the company provided the additional test results for addressing FDA letter. The title of the test report is, "The characterization of XC202 MLCC Made in ". They are five test groups in this report:

Dielectric Aging test (Part of the Group C)

(b) (4)

Based on the company claims, all the pre-market component tests are passed.

SOFTWARE: N/A

CLINICAL DATA: N/A

CONCLUSION

Based on the information in the file (PMA/S and PMA/S/A01, the company has provided appropriate data to demonstrate that XC202 is acceptable to be used in the pulse generator systems.

RECOMMENDATION – I recommend that this PMA/S supplement with the Amendment 1 to be **Approve.**

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Date

Reviewer

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Mitchell Shein **Date**
Chief, PDLB