DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

DATE: August 12, 2011

TO: The Record

FROM: [redacted] Lead Reviewer
CDRH/ODE/DCD/PDLB

SUBJECT: P980016/S298
P010031/S252
Hybrid Design and Manufacturing Changes
Medtronic

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RECOMMENDATION: APPROVAL

Signature	*Date*	*Signature*	*Date*
[redacted]		Mitchell Shein	
Lead Reviewer, PDLB		Branch Chief, PDLB	

BACKGROUND

The following is a lead review of a premarket approval (PMA) application supplement for design, materials, and manufacturing changes to the hybrids used in the devices below.

PMA Number	Product Family	Alias*1	Model Numbers
P010031	Consulta®	D2, Gen2	D224TRK
	Maximo® II	D2, Gen2	D284TRK
	Concerto® II	D2, Gen2	D274TRK
	Protecta™ XT CRT-D	D3, Gen3, Adams	D314TRG

1 The alias may be used in place of the product family name/model name. The names should be considered synonymous.

PMA Number	Product Family	Alias*1	Model Numbers
	Protecta™ CRT-D	D3, Gen3, Adams	D334TRG
P980016	Secura®	D2, Gen2	D224DRG, D224VRC
	Maximo® II	D2, Gen2	D284DRG, D284VRC
	Virtuoso® II	D2, Gen2	D274DRG, D274VRC
	Protecta™ XT DR	D3, Gen3, Adams	D314DRG
	Protecta™ DR	D3, Gen3, Adams	D334DRG
	Protecta™ XT VR	D3, Gen3, Adams	D314VRG
	Protecta™ VR	D3, Gen3, Adams	D334VRG

The application was dated April 27, 2011 and received on April 28, 2011. This submission is a 180-day supplement. Amendment A001 was also received on July 28, 2011. Amendment A001 included a document that was inadvertently omitted in the original submission (Installation Qualification Plan EIQ-015803). It also included a statement that Medtronic does not intend to amend the submission to include additional models. The original submission stated the intention to amend this submission to include additional models if they were approved prior to this submission being approved.

The hybrid substrate layout and hybrid component hardware of the devices covered under this submission are identical except for the firmware differences between the Gen2 and Adams hybrid platforms. For the purposes of this submission, these two hybrid hardware platforms are identical. All design, process, material, and component changes covered under this submission were first developed and evaluated on the D2 platform. These exact changes were carried forward to the Adams platform.

The hybrid subassemblies used for currently approved models are based on full CRT functionality and therefore include left ventricular pacing and/or right atrial sensing and pacing circuitry that is unused in dual chamber (DR) and single chamber (VR) models. This unused circuitry will be either removed or replaced with other components to reduce cost for DR and VR models. This will require the creation of unique DR and VR hybrid subassemblies. Within this submission this is referred to as depopulating hybrids (Depop). This also requires less device laser ribbon bonds for circuitry not functionally used in DR and VR devices.

This submission also includes various materials and process changes and associated minor design changes that will improve manufacturing throughput and reduce the overall cost to manufacture the D2 and Adams device models covered under this submission. These changes are referred to as High Power Lean Line or (b) (4) Changes included as part of (b) (4) include:

- Changes in adhesives (conductive and non-conductive) for improvements in moisture sensitivity level (MSL) rating.
- Change from (b) (4) mil (b) (4) bonding to (b) (4) mil (b) (4) bonding for improvements in bonding manufacturing efficiency and process capability control.
- Printed Wiring Board attach pads with thicker (b) (4) to accommodate (b) (4) bond process.

- Replacement of the hard (b) (4) protective encapsulant process with a (b) (4) (b) (4) protective encapsulant to improve manufacturability and process control.
- Minor modifications to Printed Wiring Board routing to accommodate component modifications, manufacturing process and materials changes.
- Process flow changes to remove a (b) (4) bake process due to (b) (4) compliant material sets.

In addition, there are two minor design improvements:

- Minor modification at the vendor to the transceiver transistor design in the (b) (4) RF Module used for distance telemetry communications to improve vendor yield. This change also applies to current hybrid subassemblies.
- Replacement of the (b) (4) high voltage FET with (b) (4) high voltage FET as an electrical (b) (4)

to review the submission.

REVIEW TEAM

The following CDRH individuals contributed to the review of this submission:

	ODE/DCD/PDLB - lead reviewer
,	ODE/DCD/PDLB - engineering consult (**No formal review memo provided;** comments were provided for Hybrid Reliability Testing and System/Sub-System testing)
	OC/DOEB - manufacturing OC consult

INDICATIONS FOR USE

The indications for use have not changed.

DEVICE DESCRIPTION

The device description from the submission:

The final device form and function are not impacted by the changes covered by this submission.

The Consulta, Maximo II, Concerto II, Protecta XT CRT-D and Protecta CRT-D devices under P010031 are triple chamber multiprogrammable implantable cardioverter defibrillators (ICDs).

The Maximo II, Secura, Virtuoso II, Protecta XT DR and VR and Protecta DR and VR devices under P980016 are single chamber and dual chamber multiprogrammable implantable cardioverter defibrillators (ICDs).

All of these devices use both near field and radio frequency (RF) telemetry for communication between the implanted device and programmer.

CHANGES

The changes covered by this submission are intended to reduce cost and improve manufacturability of these devices. None of the changes covered under this submission are intended to improve field performance. All of these changes are related to the hybrid subassembly and these changes do not impact the final device form or function.

Design Changes

The design changes described below are grouped into 3 categories: replacement/removal of components, design changes to support manufacturing process improvements and other design changes that are unrelated to the two previous categories.

Design changes related to replacement/removal of components

Removed and replaced components (Depop): The hybrid subassemblies used for currently approved models are based on full CRT functionality and therefore include left ventricular pacing and right atrial sensing and pacing circuitry that is unused in dual chamber (DR) and single chamber (VR) models. The unused circuitry will be either removed or replaced with other components to reduce cost for DR and VR models. Initially the unused pacing hold capacitor circuitry was replaced with resistors to provide a low impedance path to ground to reduce noise coupling. During evaluation testing (eDET) for the DR and VR component depopulation phase of the project, a difference between EGM noise performance on depopulated hybrids versus fully populated hybrids was noted. The cause for this EGM noise was determined to be an interaction introduced by the programmer software used to program in-office temporary tests. To correct this behavior, the resistor was replaced with a low value (b) (4) nF) (b) (4) capacitor such that during the temporary in-office tests the capacitor would be able to be charged to the programmed voltage and stop the pacing charge pump. The (b) (4) nF capacitance replaces the original (b) (4) uF capacitors in positions C44 and C38 on the currently approved hybrid. The (b) (4) uF pacing hold circuitry capacitance is unchanged for chambers that actively pace in the (b) (4) hybrid subassemblies. No substrate changes were required to implement this change.

The network routing associated with the removed components was tied to ground (IVSS/VSS) via top-layer metal or low-valued resistors to reduce the chance of noise coupling into the hybrid.

In addition, the unused left ventricle and/or atrial bond pad array connections are not connected to the device feedthrough to further reduce noise coupling into the system in DR and VR models. By not connecting the unused circuitry on the VR hybrid to the device feedthrough, the overall device input capacitance was reduced enough to impact an extreme use-case VIZ accuracy performance requirement. This impact was only to the VR models. To compensate, the device input capacitance was increased by changing the HVB channel capacitance on the hybrid from (b) (4) to (b) (4) for the (b) (4) configured device only. Changing the capacitance value allows the VIZ accuracy requirement to be met without affecting other device functionality/requirements.

DVDD supply cap (C301): The current (b) (4) hybrid uses (b) (4) (b) (4) uF capacitors in parallel (effective capacitance of (b) (4) uF) for the (b) (4)) on the hybrid. One of these capacitors (b) (4) is removed on all (b) (4) hybrid subassemblies. A design evaluation and subsequent verification testing has determined that the hybrid functionality and system requirements is met successfully with (b) (4) uF capacitor.

Design changes related to (b) (4)

(b) (4) **:** To accommodate the Transfer Mold process tooling, (b) (4) was used to cover the non-populated component pads and non-metal areas. Additionally, (b) (4) will be applied under the (b) (4) to allow automated solder print inspection for component. In addition, the tooling alignment holes on the hybrid coupon had (b) (4) pulled back (b) (4) mils

around the opening. This was to prevent a low-level visual inspection scrap occurrence of (b) (4) (b) (4) chipping during hybrid electrical testing.

Minor Layout Changes: The following minor layout changes were included to support the (b) (4) process capabilities:

- Layout changes to add additional spacing between the IC's on ICA side (IC Assembly side) to accommodate (b) (4) process capability.
- Removal of unused wire bond options from the hybrid substrate for the (b) (4) IC to reduce potential manufacturing errors.
- Minor shift in position of (b) (4) of (b) (4) Zener diodes to accommodate (b) (4) overmold process. The shift was implemented by moving (b) (4). There were no (b) (4) because of this change.

Other non-(b) (4) design changes

(b) (4) **Voltage FET (**(b) (4) The current D2 hybrid (b) (4) uses an (b) (4) (b) (4) FETs for IC voltage regulation in the high voltage circuitry in position (b) (4) Recently, (b) (4) sold the (b) (4) die to a different manufacturer. As a result, a voltage equivalent FET (b) (4)) will be used in place of the (b) (4). The (b) (4) (b) (4) is already used in the current hybrid ((b) (4)) in other locations.

(b) (4) **RF Module** (b) (4) A minor design modification to improve vendor yield was made at the vendor to the (b) (4) design in the (b) (4) RF Module (RFM) used for distance telemetry communications. The (b) (4) RF module is a (b) (4) (b) (4) designed and developed by (b) (4) nc. The new production hybrid subassemblies will use either the current (b) (4) RF Module ((b) (4) or a new (b) (4) RF Module (b) (4) . Because the two versions of the (b) (4) RF Module are electrically and mechanically equivalent, this submission also seeks approval to use the new revision of the (b) (4) RF Module on the existing hybrid subassemblies.

The new alternate RF Module component will incorporate an IC fabrication process change to the transceiver IC inside the module to mitigate a potential electrical test yield issue at the manufacturer. The change involves moving from a (b) (4) in the current component ((b) (4) to an industry standard single buried layer when fabricating the enhanced (b) (4) (b) (4) in the circuit ((b) (4)). No field issues were attributed to this supplier process change. This change will allow either the current (b) (4) or proposed (b) (4) part to be used on the proposed production hybrid subassemblies. There are no functional or test differences between the two final components. This change is only to improve IC transceiver yield at the vendor. This process was already qualified at the vendor for other components.

Hybrid substrate layout: A capability analysis determined that the hybrid to device feedthrough spacing can vary enough to develop a high voltage potential scenario from the feed through pads to the hybrid. This scenario is only applicable on devices that contain the DR and VR depop hybrids. To eliminate the potential arcing scenario, the hybrid test traces for unused pacing/sensing chambers were pulled back inside the network (b) (4) mils. In addition, the (b) (4) (b) (4) (LRB) pads on the hybrid for the non-populated chambers were disconnected from ground potential. These changes were evaluated under (b) (4) testing.

Moisture Sensitivity Level

Moisture Sensitivity Level (MSL) is an industry standard for the amount of time moisture sensitive materials can be exposed to ambient room conditions. As components are exposed to higher temperatures such as solder reflow conditions, any trapped moisture can expand and result in delamination of the hybrid substrate from the die, wire bond damage, or component damage.

The JEDEC standard for Moisture/Reflow Sensitivity Classification for Plastic Integrated Circuit (IC) SMDs defines levels of moisture sensitivity that set limits for the allowable period

of time for materials before they are subject to (b) (4) such as (b) (4) (b) (4) . The current hybrid manufacturing line uses materials and processes that are (b) (4) compliant; which allows (b) (4) for assembly before re-bake. The new (b) (4) (b) (4) is (b) (4) compliant which allows (b) (4) at (b) (4) t conditions prior to exposure to (b) (4) . The change to (b) (4) compliance is accomplished through the use of (b) (4) compliant materials and through process changes.

Component and Material Changes

Various material and process changes were made to improve manufacturing throughput and reduce the overall cost to manufacturing.

Component changes

The changes can be grouped into 5 high level categories; new hybrid substrates, removal or replacement of unused components in DR and VR devices, removal of an unnecessary (b) (4) uF DVDD supply capacitor ((b) (4) replacement of the (b) (4) high voltage FET (b) (4) with an electrically compatible FET, and an alternate RF Module ((b) (4) from the vendor (b) (4) .

1. **New hybrid substrates:** There will three new hybrid printed wiring board (PWB) substrates; one for each model type (CRT, DR, and VR). These new PWB's incorporate the new routing and pad layouts to support the design, component, and material changes covered under this submission.
2. **Removed and replaced components** in DR and VR devices**:** The hybrid subassemblies used for currently approved models are based on full CRT functionality and therefore include left ventricular pacing and right atrial sensing and pacing circuitry that is unused in dual chamber (DR) and single chamber (VR) models. The unused circuitry will be either removal or replaced with other components to reduce cost for DR and VR models.
3. **Removal of an unnecessary (b) (4) uF DVDD supply capacitor (b) (4)):** An unnecessary DVDD supply capacitor is being removed in new hybrid configurations.
4. **Replacement of the (b) (4) High Voltage FET ((b) (4) with an electrically compatible FET:** The (b) (4) High Voltage FET is being replaced with an electrically equivalent (b) (4) FET.
5. **Alternate (b) (4) RF Module ((b) (4)** The new production hybrid subassemblies will use either the current (b) (4) RF Module ((b) (4) or a new (b) (4) RF Module (0114612007). Because the two versions of the (b) (4) RF Module are electrically and mechanically equivalent, this submission also seeks approval to use the new revision of the (b) (4) RF Module on the existing hybrid subassemblies.

Material changes

The changes can be grouped into 4 high level categories: Hybrid Substrate, Adhesives, Assembly Wire, and Protective Encapsulant.

1. **Hybrid substrate material:** The substrate material for the new hybrids will be the same technology ((b) (4) substrate technology), but will be fabricated with (b) (4) bond (b) (4) to accommodate the (b) (4) bond process. The current hybrid has a (b) (4) minimum (b) (4) thickness. The new hybrid substrate material will be fabricated with a (b) (4) um (b) (4) thickness.
2. **Adhesives:** The new hybrids will be manufactured using new conductive and non-conductive adhesives that meet (b) (4) moisture sensitivity level (MSL).
3. **Assembly wire:** The assembly wire used for making electrical connections between ICs/die and substrate attach pads will change from (b) (4) mil (b) (4) to (b) (4) mil (b) (4) . The (b) (4) bond process provides better process control and lower loop heights which is needed for compatibility with the Transfer mold process.
4. **Protective Encapsulant:** The current hybrids (b) (4)) use an (b) (4) form that is attached to the hybrid coupon with pressure sensitive

adhesive to define the form for the hard die coat protective encapsulant during the dispense and cure processes. The new hybrids will use a new transfer mold process commonly referred to as over molding to apply a new (b) (4) compliant encapsulant. The Transfer Mold process does not use the (b) (4).

Process changes

Figure 1 in the submission depicts the current and new hybrid process flows. The process changes apply to all three new production hybrid subassemblies for (b) (4). None of the changes to the hybrid manufacturing process affect the device assembly process or the device final form or function. The hybrid subassembly manufacturing process changes covered under this submission are listed below:

- (b) (4) bonding
- (b) (4) processes
- Protective Encapsulent
- (b) (4) mil (b) (4) bonding
- Assembly coupon configuration
- Die attach adhesive cure process
- (b) (4) Cleaning
- (b) (4) Inspection

The manufacturing process changes at the vendor are listed below:

- Hybrid attach (b) (4)

HARDWARE/FIRMWARE

Component and material qualification testing

All new hybrid components and materials were subjected to (b) (4) and qualification testing. These components and materials include:

- (b) (4) Hybrid Substrate
- Conductive Die Attach Adhesive
- Non-Conductive Die Attach Adhesive
- (b) (4) mil (b) (4)
- Epoxy Mold Compound (EMC)
- (b) (4) RF Module

The hybrid component and material qualification plan and qualification reports were reviewed and found to be adequate. There were no false or confirmed failures. The deviations associated with the Conductive Die Attach Adhesive and with the Non-Conductive Die Attach Adhesive were adequately rationalized and found to be of no concern.

The new material and component (b) (4) documents were also reviewed and found to be adequate.

Hybrid and Device Reliability Testing

The new hybrid designs were subjected to reliability testing. This reliability testing is grouped into (b) (4) of testing and (b) (4) similarity exercise:

- (b) (4) testing of low power circuitry changes
- (b) (4) testing of high and low power circuitry, and RF Module
- Reliability by Equivalency for component change in Left Ventricular and Atrial Pacing charge pump low and high power circuitry
- High voltage FET ((b) (4)) as a replacement component for the (b) (4)

All test issues have been resolved. None of the test issues were design related. During Hybrid Reliability testing there were cases of (b) (4) failures. Per the sponsor:

> (b) (4)
>
> *Because the elevated tantalum capacitor leakage is expected under the additional stress that the component was subjected to during hybrid reliability testing, and because there was no design changes related to these components, there is no reliability concern related to these failures.*

Additional information was asked from the sponsor regarding a specific (b) (4) capacitor failure in test report (b) (4). This failure had more extreme leakage and required further analysis. The general statement about (b) (4) capacitor failures did not apply for this case. This information was reviewed and found to be acceptable.

also requested additional information on how the (b) (4) capacitors were qualified before and after the defect was corrected. The sponsor responded that there were no changes to the component under this project and the vendor process improvements occurred prior to this project. This information was reviewed and found to be acceptable.

The remaining hybrid reliability plans and reports were reviewed and found to be adequate. There were instances of false test failures and confirmed failures. All failures were reviewed. The explanation by the sponsor that these failures were not design related was found acceptable.

The Hybrid/Device Assembly and Design (b) (4) documents were also reviewed and found to be acceptable.

System/Sub-System Testing

System and sub-system testing was performed at both hybrid and device levels. This testing included:

- Electrical Design Verification Testing (eDVT) at both hybrid and device levels
- Electrical Design Evaluation Testing (eDET) at both hybrid and device levels
- Design Assurance Unit testing (DAU) at the device level
- System Test at the device level

The System/Sub-System plans and reports were reviewed and found to be adequate. There were instances of false test failures in the DAU test. There were 22 hybrids accidentally placed in the wrong configuration state and required a modified test flow to correct. The explanation by the sponsor was found acceptable. There were no other false or confirmed failures.

EMC/EMI

EMC/EMI testing was included as a part of the System/Sub-system tests. It was performed under Device Assurance Unit (DAU) testing. The test plan is SJ09-001 and the test report is XC06JAN10. Both of these documents were reviewed and found to be adequate. There were no failures related to EMC/EMI.

MANUFACTURING

Process Qualification testing

All new hybrid manufacturing processes were subjected to (b) (4) and process qualification testing. These processes include:

- (b) (4) Bond
- (b) (4) Bond
- Transfer mold (Overmold)

The manufacturing process qualification was reviewed by [redacted] of OC. In her review memo dated July 15, 2011, she states that process qualification appears to be adequate.

The New (b) (4) Processes (b) (4) documents were included in the submission. Per [redacted]'s email dated July 21, 2011, it was not necessary to see the (b) (4) documents since Medtronic had adequately summarized how they made risk-based determinations. The same is true for the End Product Risk Reports.

Equipment Installation Qualification Testing

IQs were also performed on all equipment that was moved from the existing line that was used in (b) (4) The (b) (4) IQ testing was originally performed for MTC Building (b) (4). The line has since been moved to Building (b) (4). The (b) (4) and (b) (4) hybrids are built on the same manufacturing line. Equipment Installation Qualification included: installation, environmental/occupational health safety, traceability/history records, calibration, and maintenance.

The equipment installation qualification was reviewed by [redacted] of OC. In her review memo dated July 15, 2011, she states that the deviations appear to be adequately addressed and the equipment installation qualification appears adequate.

Manufacturing Test Software

Various Test System software changes were required to support the Depop and (b) (4) changes covered under this submission. The manufacturing test software Verification and Validation plans and reports were reviewed by [redacted] of OC. In her email dated July 21, 2011, she states that the plans and reports appear adequate.

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Software
- Biocompatibility
- Clinical
- Human Factors
- Statistical
- Animal Testing
- Packaging, sterilization, shelf-life
- Labeling
- Post-market issues

SUMMARY OF INTERACTIONS

June 10, 2011: Overview of submission sent by sponsor
July 11, 2011: Document EIQ-015803 from sponsor via email. It was also formally submitted as Amendment A001.
July 12, 2011: Spreadsheet containing summary of test failures and deviations from sponsor
July 19, 2011: Additional information request to sponsor
July 25, 2011: Response from sponsor to additional information request.

CONCLUSION/RECOMMENDATION

The results of the non-clinical studies confirm that there are no new or increased risks associated with these changes. The component, subassembly, and device qualifications demonstrate that the material, process, and minor design changes will continue to meet all the design and manufacturing requirements. Based on these studies, I believe that Medtronic has determined that their Hybrid Design and Manufacturing changes are both safe and effective.

I recommend that the sponsor receive an **APPROVAL** letter.