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

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

SUMMARY of P980016/S280 and P890003/S214

Medtronic Protecta™ XT VR D314VRM, Protecta™ VR D334VRM, Secura® VR D204VRM, Maximo II® VR D264VRM ICD systems, Model 9995 Application Software v7.3, Model SW009 Application Software v1.0 Systems Medtronic CareLink Monitor Model 2490C, CardioSight® Reader Model 2020A, and Model 2491 DDMA

Medtronic, Inc.

BACKGROUND/REASON FOR SUPPLEMENT:

The company requests the approval of the above ICD systems with the DF4 header, and the external systems (with the application software) for the interfaces (communications) with the ICD systems. *Note: Medtronic claims only the DF4 and related interfaces were the changes in the original subject file.*

INDICATIONS FOR USE:

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

Protecta XT VR D314VRM

The Protecta XT VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure.

Notes:
The ICD features of the device function the same as other approved Medtronic market released ICDs.

Due to the addition of the OptiVol diagnostic feature, the device indications are limited to the NYHA functional class II/III heart failure patients who are indicated for an ICD.

The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.

Protecta VR D334VRM

The Protecta VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure.

Secura VR D204VRM

The Secura VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure.

Notes:
The ICD features of the device function the same as other approved Medtronic market released ICDs.

Due to the addition of the OptiVol diagnostic feature, the device indications are limited to the NYHA functional class II/III heart failure patients who are indicated for an ICD.

The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.

Maximo II VR D264VRM

The Maximo II VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure.

DEVICE DESCRIPTION:

The Protecta XT / Protecta / Secura / Maximo II VR DF4 devices are single chamber multiprogrammable, implantable cardioverter defibrillators (ICDs) monitor and regulate a patient's heart rate by providing ventricular tachyarrhythmia detection and therapies, rate-responsive bradycardia pacing and/or atrial tachyarrhythmia detection and therapies.

The following identifies the single chamber ICD device models and brand names.

Protecta™ XT VR Model D314VRM
Protecta™ VR Model D334VRM
Secura® VR Model D204VRM

Maximo® II VR Model D264VRM

The Protecta XT / Protecta VR DF4 devices contain the same hardware, firmware and use the same software application as the predecessor Protecta XT / Protecta DF1 devices. The Secura/Maximo II VR M-4 devices contain the same hardware, firmware and use the same software application as the predecessor Secura / Maximo II DF1 devices. The only difference for the VR DF4 devices from the DF-1 predecessors is that the one IS-1 and two DF-1 ports have been replaced by one DF4 port in the connector module. The length of the antenna was increased a slight amount to allow space in the header for the DF4 port.

The changes for the subject file:

The Protecta XT / Protecta VR DF4 devices are based on the Protecta XT / Protecta VR DF1 devices (approvable December 3, 2010 P010031/S171 and P980016/S211). The Secura / Maximo II VR DF4 devices are based on the Secura / Maximo II DF1 devices (P980016/S114, approved March 17, 2008). The following provides an overview of the changes:

Device DF4 Connector Module:
Modified Connector module to replace IS-1/DF-1 ports with a DF4 connector port. To provide single chamber ICDs that comply with the ISO 27186:2010 standard.

Manuals:
Updated to describe modified connector instructions. To describe modified connector implant instructions.

Labels:
Updated to describe new model information. To support new model numbers and DF4 connector symbols.

TESTING:

The company provided the test plan and a summary test report of the system tests. The summary test report contains the brief description, claiming all the tests are passed, and the device manuals were verified, etc.

SOFTWARE: N/A

CLINICAL DATA: N/A

CONCLUSION:

Based on the information in the file and the FDA policy, the company has provided the appropriate data to demonstrate the DF4 connector for the ICD systems in this file.