JUN - 8 2011

510(k) SUMMARY

K110693

Date Prepared:	March 10, 2010
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 8200 Coral Sea Street NE Mounds View, MN 55112
Contact:	Rachel U. Libi Sr. Principal Regulatory Affairs Specialist
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Proprietary Name:	Paceart Optima™ System Software
Common Name:	Pacemaker Waveform Analyzer and Digital Electrocardiograph
Device Classification	Class II, 21 CFR 870.2340, 870.2920, 870.3640, Pacemaker Waveform Analyzer and Digital Electrocardiograph Class I, 21 CFR 880.6310, Medical Device Data System (MDDS)
Product Code:	DPS, DXH, KRE and OUG

Summary of Substantial Equivalence

The intended use, design, materials and performance of the Paceart Optima™ System Software are substantially equivalent to the Paceart® System Software, which was cleared as part of the following predicate device/system.

- Medtronic Paceart System cleared via 510(k), K024278, on May 29, 2003

Device Description

The Medtronic Paceart Optima System Software, Model POS12D, is intended for use with the Medtronic Paceart System, previously cleared per K024278. The Paceart System is a 12-lead electrocardiograph, transtelephonic receiving station, and a clinic management tool that organizes patient, device and programmer information. The Paceart System is designed to integrate data from implanted cardiac device programmers, pacemaker transmitters, cardiac event recorders, and remote data networks, such as the Medtronic CareLink® Network, into a single patient record, enabling clinicians to conduct their daily work through commonly formatted data and clinic workflow tools. Note: The Paceart System will also be marketed and referred to as the Paceart Optima System when using the Paceart Optima System Software.

The Paceart System consists of hardware and software. There are no design or process changes to the hardware components of the Paceart System as part of this submission. Therefore, the subject of this 510(k) submission is for the Paceart Optima System Software only and contains only information on the software changes.

Indications for Use

The Paceart System is intended for use as a 12-lead electrocardiograph, pacemaker artifact analyzer, and transtelephonic ECG receiving station. It also acts as a database for cardiac patients with or without pacemakers or Implantable Cardioverter Defibrillators.

Technological Characteristics

Intended use, design, materials, performance and technological characteristics are substantially equivalent to the predicate devices referenced.

Summary of Testing

Software verification testing and validation testing is performed to demonstrate the Paceart Optima System Software meets established performance criteria and to support equivalency to the referenced predicate device.

Conclusion

Medtronic considers the Paceart Optima System Software to be substantially equivalent to the previously cleared Paceart System Software (reference K024278) through the data and information presented. No new safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic, Inc.
c/o Ms. Rachel U. Libi
Sr. Principal Regulatory Affairs Specialist
8200 Coral Sea Street
Mounds View, MN 55304

JUN - 8 2011

Re: K110693
Trade/Device Name: Paceart Optima™ System Software
Regulation Number: 21 CFR 870.3640
Regulation Name: Indirect pacemaker generator function analyzer
Regulatory Class: Class II (two)
Product Code: KRE, DPS, DXH, and OUG
Dated: May 18, 2011
Received: May 19, 2011

Dear Ms. Libi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K110693

Device Name: Paceart Optima™ System Software

Indications for Use: The Paceart System is intended for use as a 12-lead electrocardiograph, pacemaker artifact analyzer, and transtelephonic ECG receiving station. It also acts as a database for cardiac patients with or without pacemakers or Implantable Cardioverter Defibrillators.

Prescription Use X AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110693