K024278

MAY 2 9 2003

510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Date Prepared:	December 20, 2002
Submitter:	Medtronic, Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432
Contact:	Karen Ruth-Jarmon Sr. Regulatory Affairs Manager
Telephone:	(763) 514-3783
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E-mail:	karen.ruth.jarmon@medtronic.com
Proprietary Name:	Paceart® System
Common Name:	Pacemaker Waveform Analyzer and Digital Electrocardiograph
Device Classification:	Class II, 21 CFR § 870.2340, 870.2920, 870.3640
Product Codes:	DPS, DXH, KRE

Device Description

The Medtronic Paceart® System is a personal computer based pacemaker-testing system, a 12-lead electrocardiograph, and a transtelephonic receiving station. It provides data that can be used to analyze implanted pacemaker performance based on electrocardiographic measurements, either taken directly from the patient or programmer. The system can measure, store, and display any of the 12 standard leads. Reports and charts are available by means of a laser printer. The system also includes a database that collects and stores patient data. Optional software allows the device to function as an unattended transtelephonic receiving station.

The system is comprised of the following components:

- Personal Computer
- Paceart System software
- LaserJet Printer
- Parallel (TTM, Clinical, and Full)

- USB module (TTM and Full)
- Isolation transformer
- Cables

Intended 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.

Substantially Equivalent Devices

The Paceart® System is substantially equivalent to a combination of features offered by predicate systems identified in the following table.

Predicate Device	Predicate Device Manufacturer	Predicate 510(k)
Paceart CPTS-86/12	Paceart, Inc.	K915632 Decision date 04/14/1992
Paceart CardioVoice	Paceart, Inc.	K952065 Decision date 01/16/1996

Summary of Testing

The device was tested in accordance with applicable sections of AAMI/ANSI EC 11: 1991, *Diagnostic Electrocardiographic D*evices and AAMI/ANSI EC 38: 1998, *Ambulatory Electrocardiographs*. The telephone circuitry was tested to FCC CFR 47, Part 68: *Connection of Terminal Equipment to the Telephone Network*. The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* have been applied. The information provided in section 9.0 Off-The-Shelf Software was prepared in accordance with the FDA's guidance document "Off-The-Shelf Software Use in Medical Devices," issued September 9, 1999.

Conclusion

Through the data and information presented, as well as similarities to legally marketed devices, Medtronic Paceart considers the Paceart® System to be substantially equivalent to the previously discussed legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2003

Medtronic, Inc.
c/o Ms. Karen Ruth-Jarmon
Sr. Regulatory Affairs Manager
7000 Central Avenue NE
Minneapolis, MN 55432

Re: K024278
Trade Name: Paceart System
Regulation Number: 21 CFR 870.2340, 870.2920, 870.3640
Regulation Name: Pacemaker Waveform Analyzer and Digital Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS, DXH, KRE
Dated: April 28, 2003
Received: April 29, 2003

Dear Ms. Ruth-Jarmon:

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.

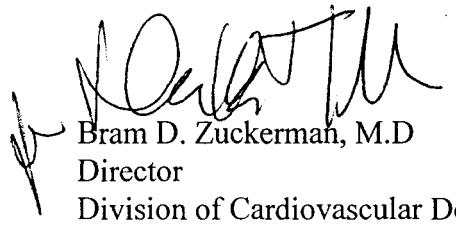
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): N/A

Device Name: Paceart® System

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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024278