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K020896
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510(k) Summary

Date:	15 March 2002
Submitter:	Osypka Medical GmbH Grossbeerenstrasse 184, 12277 Berlin, Germany
Contact Person:	Markus Osypka, Ph.D., President Osypka Medical, Inc. 7463 Draper Avenue, La Jolla, California 92037, USA Phone: (858) 459-2312 Fax: (858) 459-2353
Device Trade Names:	OSCOR™ PACE 203™ / PACE 203H™ and Accessories; ST. JUDE MEDICAL™ MODEL 3085 and Accessories; CARDIOTRONIC™ PACE 203™ and Accessories; Accessories including: XI.TME / XI.RAC Extension Cables; AS.45 Arm Strap; Quick Reference.
Common / Usual Names:	Dual-Chamber External Pulse Generator, Dual-Chamber Temporary Cardiac Pacemaker; Extension Cable, Patient Cable. Arm Strap.
Classification Names:	870.3600 Pulse-Generator, Pacemaker, External 870.2900 Cables, Transducer and Electrode
Predicate Devices:	K910237 MEDTRONIC™ MODIFIED MODEL 5330 A-V Demand Pulse Generator K893633 MEDTRONIC™ MODEL 5330 External A-V Sequential Demand Pulse Generator K970497 OSCOR™ D-1 / D-3 / D-5 / D-9 / D-10 Extension Cables PACE 101H Arm Strap K923621 OSCOR™ DX-2 / D-5 / D-10 Extension Cables PACE 100H Arm Strap
Device Description:	The PACE 203 / PACE 203H / MODEL 3085 is a dual-chamber external cardiac pacemaker with atrial controlled timing for routine temporary heart stimulation. Synchronous and asynchronous modes of atrial, ventricular and A-V sequential stimulation are available for treatment of acute brady-arrhythmia and for pre-, intra-, and post-operative stimulation of the heart. The stimulation parameters are easily adjustable by rotating dials through a wide range of values. The PACE 203 / PACE 203H / MODEL 3085 offers the possibility for atrial overdrive stimulation, or rapid atrial pacing, for terminating supra-ventricular tachycardia. The rate of the overdrive stimulation is adjustable within a wide range and is independent of the selected stimulation rate. The overdrive rate can be determined before and changed during overdrive therapy. If required, overdrive stimulation can be initiated with the touch of a button. The overdrive stimulation is indicated optically and acoustically.

The battery operated device can be affixed to the patient's arm by the arm strap included. The housing is protected against accidental liquid spills.

The functional design of the PACE 203 / PACE 203H / MODEL 3085 allows safe and easy operation with regards to all requirements of DDD stimulation.

The PACE 203 / PACE 203H / MODEL 3085 further offers the following features:

- During battery changes, stimulation will be maintained for at least 30 s.
- A non-volatile memory keeps any desired stand-by program ready for use, even if the device is shut off.
- A standard program, which can be individualized, is available for each primary pacing mode.
- An emergency program can be "called up" by pressing an emergency key.
- A burst- and a ramp function are available for atrial overdrive-stimulation.
- An Unlock/Lock button protects against accidental change of the set parameters.
- The set parameters and (error) messages are shown on a liquid crystal display.
- The detection of the intrinsic heart activity as well as the emission of stimulation impulses are shown separately by blinking LEDs for both atrium and ventricle. Additionally, a beep-tone can be switched on whenever desired.
- System malfunctions that occur are indicated optically and acoustically.
- A lead surveillance system indicates interruptions and short circuits.
- When a battery change is required, optical and acoustic alerts are provided.
- During dual chamber pacing, an automatic mode for adapting A-V delay, maximum tracking rate (MTR), and PVARP is available.
- An automatic mode for adjusting the sensitivity in both the atrium and ventricle may be chosen.
- A Pause function is available for easy determination and measurement of the patient's intrinsic heart activity.

The Series XI Extension Cables support proper connection of the PACE 203 / PACE 203H / Model 3085 to various types of pacing lead systems (accessories).

The Series AS Arm Straps ensure proper attachment of the PACE 203 / PACE 203H / Model 3085 to the patient's arm (optional accessory).

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Intended Use:	The PACE 203 / PACE 203H / MODEL 3085 external pulse generator / dual-chamber temporary pacemaker is designed to be used with cardiac pacing lead systems for temporary atrial or ventricular or A-V sequential pacing. The PACE 203 / PACE 203H / MODEL 3085 has applications where such pacing modes are indicated for therapeutic, prophylactic, or diagnostic purposes. Specific indications include, but are not limited to, the following: • Sick Sinus Syndrome; • Bradycardia with congestive heart failure; • Complete heart block; • Acute myocardial infarction complicated by heart block; • Sinus bradycardia; • Cardiac arrest with ventricular asystole; • Atrial and/or ventricular ectopic arrhythmia; • Postoperatively after cardiac surgery; • Temporary application during implantation or exchange of permanent pacemaker. Indication for atrial overdrive stimulation (rapid atrial pacing): • Supra-ventricular tachycardia. The PACE 203 / PACE 203H / MODEL 3085 can be used to measure atrial or ventricular voltage stimulation thresholds and determine the approximate P wave potentials sensed via the atrial pacing lead electrodes and the approximate R wave potentials sensed via the ventricular pacing lead electrodes.
Technology:	The PACE 203 / PACE 203H / MODEL 3085 and accessories and the MEDTRONIC MODEL 5330 have the same fundamental technological characteristics in design, material, and energy source. The aforementioned devices are stand-alone devices that provide temporary atrial or ventricular or A-V sequential pacing therapy, including a demand ventricular pacing function. The aforementioned devices are battery powered and include defibrillation shock protection and a safety-lock on-off switch. Indicator lights flash to show atrial and ventricular sensing and atrial and ventricular pacing functions. Compared to the MEDTRONIC MODEL 5330, the PACE 203 / PACE 203H / MODEL 3085 adds the following functions: • Atrial sensing (demand atrial pacing); • Optional P Wave / R Wave peak amplitude measurements upon a key stroke; • Optional AUTO SENSE function;

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	• Continuous display of battery condition during operation; • After at least 30 minutes of operation, continuous pacing therapy is maintained during a battery change for at least 30 seconds. • Insulated connector terminals matching the protected pins of the Series XI Extension Cables (meet 21 CFR Part 898 performance standard).
Summary Bench Testing:	PACE 203 / PACE 203H / MODEL 3085 and MEDTRONIC MODEL 5330 were subject to bench testing using a simulator. Bench testing compared the performance of both devices against their specifications and determined substantial equivalence. Bench testing also validated safety and effectiveness of the insulated connector terminals matching the protected pins of the Series XI Extension Cables.
Summary Clinical Evaluation:	The clinical evaluation validated safety and effectiveness of the PACE 203 / PACE 203H / MODEL 3085. No serious adverse event related to the PACE 203 / PACE 203H / MODEL 3085 occurred during the course of the investigation. The optional AUTO SENSE function reliably tracks P wave and R wave peak amplitudes and adjusts the sensitivities in the atrial and, respectively, ventricular channel accordingly. Based on the recordings obtained, the PACE 203 / PACE 203H / MODEL 3085 provided corrects sensing, pacing and A-V sequential demand pacing (DDD) performance without failure.
Conclusion:	The results of the bench testing and the clinical evaluation verified the correct function of the PACE 203 / PACE 203H / MODEL 3085, and validated that the PACE 203 / PACE 203H / MODEL 3085 is as safe, as effective, and performs as well as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2002

Osypka Medical, Inc.
c/o Markus J. Osypka, Ph.D.
President
7463 Draper Avenue
La Jolla, CA 92037

Re: K020896
Trade Name: Oscor™ Pace 203/203H
St. Jude Medical™ Model 3085
Cardiotronic™ Pace 203
XI.TME and XI.RAC Extension Cables
Regulation Number: 21 CFR 870.3600
Regulation Name: Pulse Generator, Pacemaker, External
Regulatory Class: Class III (three)
Product Code: DTE
Dated: March 15, 2002
Received: March 19, 2002

Dear Dr. Osypka:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020896

510(k) Number: K020896

Device Names: OSCOR PACE 203 / PACE 203H
ST. JUDE MEDICAL MODEL 3085
CARDIOTRONIC PACE 203
XI.TME and XI.RAC Extension Cables

Indications For Use:

The PACE 203 / PACE 203H / MODEL 3085 external pulse generator / temporary pacemaker is designed to be used with cardiac pacing lead systems for temporary atrial or ventricular or A-V sequential pacing. The PACE 203 / PACE 203H / MODEL 3085 has applications where such pacing modes are indicated for therapeutic, prophylactic, or diagnostic purposes.

Specific indications include, but are not limited to, the following:

- Sick Sinus Syndrome;
- Bradycardia with congestive heart failure;
- Complete heart block;
- Acute myocardial infarction complicated by heart block;
- Sinus bradycardia;
- Cardiac arrest with ventricular asystole;
- Atrial and/or ventricular ectopic arrhythmia;
- Postoperatively after cardiac surgery;
- Temporary application during implantation or exchange of permanent pacemaker.

Indication for atrial overdrive stimulation (rapid atrial pacing):

- Supra-ventricular tachycardia.

The PACE 203 / PACE 203H / MODEL 3085 can be used to measure atrial or ventricular voltage stimulation thresholds and determine the approximate P wave potentials sensed via the atrial pacing lead electrodes and the approximate R wave potentials sensed via the ventricular pacing lead electrodes.

The XI.TME and XI.RAC Extension Cables are used with external pulse generators / temporary cardiac pacemakers and pacing system analyzers.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-The-Counter-Use ___
Per 21 CFR 801.109

Division of Cardiovascular & Respiratory Devices
510(k) Number K020896

(Optional Format 1-2-96)