OCT 3 1 2003

OSYPKA MEDICAL
Berlin, Germany • San Diego, California, USA

510(k) Summary

Date:	28 September 2003
Submitter:	Osypka Medical GmbH Grossbeerenstrasse 184, 12277 Berlin, Germany
Contact Person:	Markus Osypka, Ph.D., President Osypka Medical, Inc. 7855 Ivanhoe Avenue, Suite 226, La Jolla, California 92037, USA Phone: (858) 454-0021 Fax: (858) 454-0064
Device Trade Names:	OSCOR® PACE 101™ / PACE 101H™ and Accessories; ST. JUDE MEDICAL™ Model 3077 and Accessories; CARDIOTRONIC™ PACE 101™ and Accessories; Accessories including: XI Series™ Extension Cables: XI.TPE™, XI.TME™, XI.HWR™, XI.RAC™, XI.XTP™, XI,XHW™; AS.45™ Arm Strap.
Common / Usual Names:	SSI External Pulse Generator, Single-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:	K022939 OSCOR® PACE 101™ / PACE 101H™ External Pacemaker ST. JUDE MEDICAL™ Model 3077 CARDIOTRONIC™ PACE 101™ K970497 OSCOR® PACE 101H External Pacemaker K923621 OSCOR® PACE 100H External Pacemaker K020896 XI.TME™ and XI.RAC™ Extension Cables 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 101 / PACE 101H / Model 3077 SSI Temporary Pulse Generator is used for temporary intensive care pacing of the heart in cases of rhythm disturbances and conduction defects, including: • Treatment of bradycardia • Treatment of atrial tachyarrhythmia • Treatment of special causes of acute myocardial infarction • Pre-, intra- and postoperative pacing of the heart.

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	The PACE 101 / PACE 101H / Model 3077 can be used as either an intracardiac signal-inhibited pulse generator or as an asynchronous pulse generator. Pacing rate and amplitude can be adjusted over a wide range, conforming to actual therapeutic requirements. Sensed intrinsic activity and paced pulses are indicated optically by a light-emitting diode (LED). Additionally, acoustic signals for sensing and pacing can be switched on and off. The PACE 101 / PACE 101H / Model 3077 has two modes of high-rate pacing for the treatment of atrial tachycardia. Pacing frequency can easily doubled or quadrupled; the PACE 101 / PACE 101H / Model 3077 will then pace in asynchronous mode. An acoustic signal is automatically emitted during high-rate pacing. Errors that occur during operation are indicated optically and acoustically. A special circuit allows for automatic surveillance of the battery voltage. With the help of an LED and an acoustic signal, complete drainage of the battery can be prevented. The PACE 101 / PACE 101H / Model 3077 has an additional feature – run-away protection. Run-away protection limits the impulse emission to a maximum of 200 ppm and prevents the delivery of too high a pacing rate in the event of a defect in the frequency generator. The XI Series™ Extension Cables support proper connection of the PACE 101 / PACE 101H / Model 3077 to various types of pacing lead systems (accessories). The AS Series™ Arm Straps ensure proper attachment of the PACE 101 / PACE 101H / Model 3077 to the patient's arm (accessory).
Intended Use:	The PACE 101 / PACE 101H / Model 3077 SSI Temporary Pulse Generator is designed to be used with cardiac pacing lead systems for temporary atrial or ventricular pacing. When combined with a stimulation lead system, the PACE 101 / PACE 101H / Model 3077 SSI Temporary Pulse Generator can be used whenever temporary atrial or ventricular pacing is indicated. The device can be employed for therapeutic as well as diagnostic purposes or may be used prophylactically. Specific indications for temporary pacing include, but are not limited to: • Complete (third-degree) or intermittent heart block; • Symptomatic sinus bradycardia; • Atrial and/or ventricular ectopic arrhythmia; • Sick Sinus Syndrome (SSS); • Atrial tachyarrhythmia; • Acute myocardial infarction-induced heart block; • Stimulation during ventricular asystole; • Use during the replacement of an implantable pulse generator; • Stimulation and monitoring before the implantation of a cardiac pulse generator; • Stimulation and monitoring following heart surgery.

K033130

Technology:	The PACE 101 / PACE 101H / Model 3077 SSI Temporary Pulse Generator and its predicate device have the same fundamental technological characteristics in design, material, shape and energy source. The aforementioned devices are stand-alone devices that provide temporary atrial or ventricular demand or asynchronous pacing therapy. The aforementioned devices are battery powered. Indicator lights flash to show atrial and ventricular sensing and atrial and ventricular pacing functions. The PACE 101 / PACE 101H / Model 3077 is equipped with insulated connector terminals matching the protected pins of the XI Series™ Extension Cables and meets the 21 CFR Part 898 performance standard.
Summary Bench Testing:	The modifications made do not require additional bench testing.
Summary Clinical Evaluation:	The modifications made do not require additional clinical evaluation.
Conclusion:	The modifications made to the device are related to a revision of the Instructions for Use / User' Manual, without changing the intended use or the fundamental scientific technology. Some of the Series XI Extension™ Cables, and the AS Series™ Arm Strap, have been previously market-released in combination with the PACE 101™ Single-Chamber External Pulse Generator and PACE 203™ Dual-Chamber External Pulse Generator. Based on the limited impact of the modifications made, it is concluded that the PACE 101 / PACE 101H / Model 3077 SSI External Pulse Generator is as safe, as effective, and performs as well as the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Osypka Medical, Inc.
c/o Markus J. Osypka, Ph.D.
President
7855 Ivanhoe Avenue, Suite 226
La Jolla, CA 92037

Re: K033130
Trade Name: PACE 101/PACE 101H, Model 3077 SSI Temporary Pulse Generator
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class III (three)
Product Code: DTE
Dated: September 28, 2003
Received: September 30, 2003

Dear Dr. Osypka:

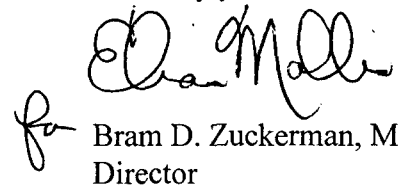
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), 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,



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

Enclosure

510(k) Number: K033130

Device Names: OSCOR PACE 101 / PACE 101H
ST. JUDE MEDICAL MODEL 3077
CARDIOTRONIC PACE 101
XI Series Extension Cables:
XI.TPE, XI.TME, XI.HWR, XI.RAC, XI.XTP, XI.XHW
AS.45 Arm Strap

Indications For Use:

The PACE 101 / PACE 101H / Model 3077 SSI Temporary Pulse Generator is designed to be used with cardiac pacing lead systems for temporary atrial or ventricular pacing.

When combined with a stimulation lead system, the PACE 101 / PACE 101H / Model 3077 SSI Temporary Pulse Generator can be used whenever temporary atrial or ventricular pacing is indicated. The device can be employed for therapeutic as well as diagnostic purposes or may be used prophylactically.

Specific indications for temporary pacing include, but are not limited to:

- Complete (third-degree) or intermittent heart block;
- Symptomatic sinus bradycardia;
- Atrial and/or ventricular ectopic arrhythmia;
- Sick Sinus Syndrome (SSS);
- Atrial tachyarrhythmia;
- Acute myocardial infarction-induced heart block;
- Stimulation during ventricular asystole;
- Use during the replacement of an implantable pulse generator;
- Stimulation and monitoring before the implantation of a cardiac pulse generator;
- Stimulation and monitoring following heart surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033130

(Optional Format 1-2-96)