



JUN 4 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mila Doskocil
Manager, Regulatory Affairs/Quality Assurance
Oscor Medical Corporation
3816 DeSoto Boulevard
Palm Harbor, Florida 34683

Re: " K970497
Trade Name: PACE 101 H; External Pacemaker
Regulatory Class: III
Product Code: 74DTE
Dated: February 7, 1997
Received: February 10, 1997

Dear Ms. Doskocil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(K) Number: K970497

Device Name: Sulzer Oscor Inc. PACE 101 H External Pacemaker

Indications for Use:

The external pacemaker PACE 101 H is designed for temporary stimulation of the heart in case of rhythm disturbances and conduction defects. According to present clinical experience, the instrument is especially suited for stimulation of the heart in the following cases:

- treatment of patients before an operation, whereby an implantable pacemaker is being inserted;
- treatment of tachyarrhythmia;
- treatment of special cases of acute myocardial infarction;
- treatment of patients after heart surgery.

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

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

OR Over-The-Counter Use

Thomas J. Callahan
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K970497