K020669

MAR 2 8 2002

OSCOR INC.
SUMMARY AND CERTIFICATION

STATEMENT REGARDING SAFETY AND EFFECTIVENESS INFORMATION

Safety and effectiveness information will be available to interested persons upon request.

CERTIFICATION AND SUMMARY

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for iridium coated tip permanent pacing leads. I further certify that I am aware of the types of problems and possible complications to which permanent pacemaker leads are susceptible, and that the following summary of the types and causes of safety and/or effectiveness problems about permanent pacing leads is complete and accurate:

Types and Causes of Safety and/or Effectiveness Problems

Intermittent or continuous loss of pacing or sensing caused by such factors as:

RELATED TO LEAD FUNCTION

1. Complete or partial dislodgment of the electrode. Lead may require surgical repositioning or removal.
2. Breakage of the conductor or its insulation. Lead may require surgical removal and/or repair.
3. An increase in thresholds.
4. Poor electrical connection to the pulse generator

RELATED TO CARDIOVASCULAR/PATIENT

1. Inadvertent engagement of the lead tip with intracardiac structures, such as the tricuspid valve or chordae tendineae.
2. Inadvertent cardiac perforation can cause:
   Phrenic nerve stimulation or diaphragmatic muscle stimulation
   Cardiac tamponade
3. Myocardial irritability may occur at implant (PVC's, ventricular tachycardia, and fibrillation).
4. Air embolism, pneumothorax, arterial puncture, and hematoma at insertion point can occur with transvenous introduction of a lead.
5. Infection. As with the introduction of any foreign object into the body, infection can result from the use of endocardial leads. Surgical removal of the lead may be required.
6. When removing an implanted endocardial lead, if the connector is cut off, the lead's insulation tubing, under sufficient traction, may separate from the lead conductor and slide off, leaving an exposed conductor coil in the heart and vein.

These complications can occur during implantation, explantation, or at any time postoperatively, and may require noninvasive or invasive management techniques.

Attached is a bibliography of the materials upon which the summary is based on.

510(K) Submitter: Mila Doskocil
Signature of Submitter: Mila Doskocil
Title of Submitter: Director of RA/QA
Name of Company: Oscor Inc.
Date: February 27, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2002

Ms. Mila Doskocil
Director of RA/QA
Oscor, Inc.
3816 DeSoto Boulevard
Palm Harbor, FL 34683

Re: K020669
Trade Name: Permanent Pacing Lead, Model Petite™
Regulation Number: 21 CFR 870.3680
Regulation Name: Permanent Pacemaker Electrode
Regulatory Class: Class III (three)
Product Code: DTB
Dated: February 27, 2002
Received: March 1, 2002

Dear Ms. Doskocil:

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.

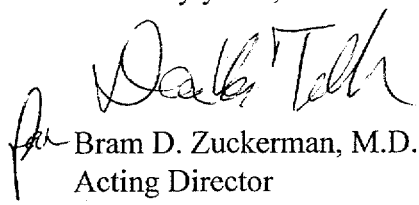
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

Attachment 2

Indications for Use Statement

510k Number (if known) -

Device Name: **Permanent Pacing Lead, Model Petite™**

Permanent pacing lead, Model Petite™ is indicated for pacing and sensing of the ventricle and/or atrium of the heart. This lead is used in conjunction with a compatible implantable pulse generator (pacemaker).

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

Concurrenceof CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020669