



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2 2004

European Custom Manufacturing B.V.
c/o Mr. Maarten Kanters
QA Manager
Oost-Om 54
P.O. Box 53
NL-5420 AB Gemert
Netherlands

Re: K033858

Trade Name: Temporary Bipolar Myocardial Pacing Wire
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent or Temporary Pacemaker Electrode
Regulatory Class: II (two)
Product Code: LDF
Dated: May 25, 2004
Received: June 28, 2004

Dear Mr. Kanters:

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.

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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) 594-4648. 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



EUROPEAN CUSTOM MANUFACTURING B.V.

Indications for Use Statement

510(K) Number: K033858

Device Name: Temporary Bipolar Myocardial Pacing Wire

Indications for use: The Temporary Bipolar Myocardial Pacing Wire functions as a temporary implant for the transmission of electrical heart pacing signals. The heart wire is placed following cardiac surgery to be in direct contact with the native myocardium while the natural heart is surgically exposed.

The wire may be used on either the atrium or ventricle.

Sincerely,

Maarten Kanters
QA Manger
European Custom Manufacturing BV

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number 160 33858

Prescription Use X
Counter Use _____
(Part 21 CFR 801 Subpart D)
Subpart C)

AND/OR

Over-The-

(21 CFR 807