K023174
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JUN 11 2003

Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed RIVER Medical RIVER-WIRE component device.

Manufacturer:

RIVER Medical, Inc.
836 NE 24th Avenue
Portland, OR 97232
PHONE: (503) 230-1280
FAX: (503) 233-1152

Contact Person: Mary Ann Greenawalt, Vice President
Legal & Regulatory Affairs

Device Name:

Trade Name: Disposable Temporary Pacing Wire

Common Name: Component to diagnostic or physiological monitoring devices

Proprietary name: RIVER Wire™

Classification: Cable, Transducer and Electrode, Patient (including Connector), Cardiovascular, LDF, Class II

Date Prepared: September 19, 2002

Device Description: The proposed device and the predicate device(s) are composed of metallic 28- to 32-gauge wire, an extruded insulation coating, a special curved needle to ease the transcutaneous placement of the electrode in the skin, and a snap-off straight needle. The leads are available in various sizes, lengths, and quantities. The predicate and proposed devices are manufactured in compliance with special controls/performance standards as dictated by 21 CFR 898; 62 FR 25497
26 USP <871> *Sutures – Needle Attachment*, <881> *Tensile Strength – Surgical sutures*, <71> *Sterility Tests*, <861> *Sutures – Diameter. ANSI/AAMI/ISO 10993-7. IEC 60601-1-Sub-Clause 6.1; IEC 601-1, Sub-Clause 4.10; IEC 601-1, Sub-Clause 44.7; IEC 60601-1, Sub-Clause 20.4, IEC 60601-2-27, Clause 20.3 ANSI/AAMI EC 53, Cl. 5.5.1; IEC 60601-1, Sub-Clause 19.4h, ANSI/AAMI EC53, Clause 5.5.2; IEC 60601-1, Cl. 21.5, IEC 60601-2-27, Cl. 21.5, UL 2601; 55; ANSI/AAMI EC53, Clause 5.5.10; IEC 60601-1, Sub-Clause 57.4a, ANSI/AAMI EC 53, Clause 5.5.6.*

Intended Use: The RIVER Medical Temporary Cardiac Pacing Wire is a nonabsorbable surgical cardiac pacer lead with dual needle intended to be used for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is SINGLE USE ONLY. The device is supplied nonsterile on OEM basis only.

Indications: The RIVER Medical Disposable Temporary Cardiac Pacing Wire is indicated for use in temporary atrial and ventricular pacing and sensing during and after cardiac surgery.

Comparison of Technological Characteristics: The proposed device, the disposable temporary pacing wire, comprises the same or similar material as the predicate device. Manufacture of this device, and QC testing, is in substantial compliance with current 21 CFR 898; 62 FR 2549726 USP <871> *Sutures – Needle Attachment*, <881> *Tensile Strength – Surgical sutures*, <71> *Sterility Tests*, <861> *Sutures – Diameter. ANSI/AAMI/ISO 10993-7. IEC 60601-1-Sub-Clause 6.1; IEC 601-1, Sub-Clause 4.10; IEC 601-1, Sub-Clause 44.7; IEC 60601-1, Sub-Clause 20.4, IEC 60601-2-27, Clause 20.3 ANSI/AAMI EC 53, Cl. 5.5.1; IEC 60601-1, Sub-Clause 19.4h, ANSI/AAMI EC53, Clause 5.5.2; IEC 60601-1, Cl. 21.5, IEC 60601-2-27, Cl. 21.5, UL 2601; 55; ANSI/AAMI EC53, Clause 5.5.10; IEC 60601-1, Sub-Clause 57.4a, ANSI/AAMI EC 53, Clause 5.5.6.*

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

RIVER Medical, Inc.
c/o Ms. Mary Ann Greenawalt
Vice President Legal & Regulatory Affairs
836 NE 24th Avenue
Portland, OR 97232

Re: K023174
Trade Name: Disposable Temporary Pacing Wire
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular permanent or temporary pacemaker electrode.
Regulatory Class: Class II (two)
Product Code: LDF
Dated: April 28, 2003
Received: May 5, 2003

Dear Ms. Greenawalt:

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.

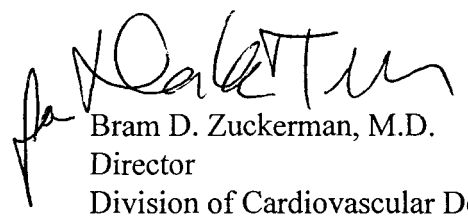
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

INDICATIONS FOR USE

510(k) (if known): K023174

DEVICE Name: Disposable Temporary Pacing Wire

Indications for Use:

The RIVER Medical Disposable Temporary Cardiac Pacing Wire is indicated for use in temporary atrial and ventricular pacing and sensing during and after cardiac surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023174