K980503

APR 10 1998

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME: Temporary Cardiac Pacing Wire

PREDICATE DEVICE NAME: Temporary Cardiac Pacing Wire

510(k) SUMMARY

Device Description

The Temporary Cardiac Pacing Wire with wave is a lead that consists of an uninsulated multifilament stainless steel wire electrode and an insulated multifilament conductor coated with blue polyethylene attached to a straight Keith needle. There is no exposed wire at the point of the swage to the straight Keith needle. The Keith needle is scored eliminating the need to cut the needle. The Keith needle is connected to an external temporary cardiac pacing or monitoring device. A 'wave' is preformed into the uninsulated distal end, then attached to a curved needle.

Continued on next page

510(k) SUMMARY, Continued

Intended Use	The Temporary Cardiac Pacing Wire with wave is intended for use in temporary cardiac pacing or monitoring. The Temporary Cardiac Pacing Wire with wave has the same intended use as predicate device Temporary Cardiac Pacing Wire (TPW).
Indications Statement	The Temporary Cardiac Pacing Wire with wave is intended for use in temporary cardiac pacing or monitoring.
Technological Characteristics	The modified device has the same technological characteristics as the predicate device. There is no change in material, insulated coating or electrical resistance.
Performance Data	Nonclinical laboratory testing was performed to determine pullout force after implantation. It was determined that the Temporary Cardiac Pacing Wire with wave has an increased resistance to pullout force after it is inserted into the myocardium when compared to the predicate device.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
Contact	Gregory R. Jones Director, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	February 6, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 1998

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Incorporated
P.O. Box 151
Somerville, NJ 08876-0151

Re: K980503
Trade Name: Temporary Cardiac Pacing Wire
Regulatory Class: II
Product Code: LDF
Dated: February 6, 1998
Received: February 9, 1998

Dear Mr. Jones:

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 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). 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 (Premarket 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 premarket 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) 594-4618. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

INDICATION FOR USE

510(k) Number (if known): K980503

Device Name: Temporary Cardiac Pacing Wire

Indications for Use: The Temporary Cardiac Pacing Wire is intended for use in temporary cardiac pacing or monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K980503

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)