AUG 26 1998

K981329

SECTION II

510(K) SUMMARY

Proprietary Name: Feth-R-Kath® Epidural Catheter
Common Name: Epidural Catheter
Classification Name: Anesthesia Conduction Catheter

Prepared: Tuesday, April 07, 1998

Epimed International, Inc.
6 Division Street
Gloversville, NY 12078

The Epimed Feth-R-Kath epidural catheter is a Class II device that is substantially equivalent to the Arrow International Flex Tip Plus® epidural catheter in design, composition, performance characteristics and intended use.

Both devices incorporate a Fluoropolymer tube encompassing a stainless steel spring. The Arrow Flex Tip Plus® is a 19G catheter 36 inches in length. The Feth-R-Kath will be offered in both a 19G and 20G size each with a length of 36 inches. The Flex Tip Plus® has a .019 inch inner diameter while the Feth-R-Kath has a .021 inch inner diameter.

The bench testing performed on each epidural catheter to compare performance characteristics confirmed that the Feth-R-Kath either met or exceeded the performance characteristics of the Flex Tip Plus®. The catheters were tested with regard to tensile strength, percent elongation, flow rate and kink resistance and the results were compared to the predicate device as well as other epidural catheters currently on the market.

The 20G version of the Feth-R-Tip is identical to the 19G Feth-R-Tip in all regards except dimensional specifications. The smaller outer diameter creates a smaller inner diameter. The 20G catheter was tested for performance characteristics in an identical fashion as the 19G. These results were compared to other 20G epidural catheters currently on the market as well as the predicate device. Epimed International, Inc. determined the 20G Feth-R-Kath was substantially equivalent in performance to the predicate device and posed no additional safety or effectiveness issues.

The intended use of the subject device is equivalent to the predicate device. The catheter is designed to be introduced into the epidural space via an epidural needle. Connection to an epidural filter or syringe is facilitated by attaching a connector to the proximal end. Both catheters are sold as sterile, single-use devices. Both catheters are radiopaque and designed to administer continuous epidural and/or caudal anesthesia. The Epimed Feth-R-Kath has been proven to be non-pyrogenic and biocompatible in it's finished state.

All known problems associated with the safety and/or effectiveness of the device have been investigated and evaluated. The Feth-R-Kath poses no additional risks in safety and/or effectiveness than the Arrow Flex Tip Plus® epidural catheter. The risks or hazards associated with the device are clearly defined on the products' label as warnings and/or precautions.

Submitted By: Epimed International Incorporated
6 Division Street
Gloversville, NY 12978

Contact: Donald R. Henderson

Donald R. Henderson, Director RA/QA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1998

Mr. Donald R. Henderson
Epimed International, Inc.
6 Division Street
P.O. Box 1128
Gloversville, NY 12078

Re: K981329
FETH-R-KATH
Regulatory Class: II (two)
Product Code: 73 BSO
Dated: June 23, 1998
Received: June 25, 1998

Dear Mr. Henderson:

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) 594-4648. 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/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

510(k) Number (if known): K 981329

Device Name: Feth-R-Kath

Indications For Use:

The Epimed Feth-R-Kath epidural catheter is intended for administration of local anesthetics into the epidural space to provide continuous epidural or caudal anesthesia for up to 72 hours.

(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

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)