K023140

AUG 15 2003

Section II

510(K) Summary

Company Information:

Epimed International, Inc.
141 Sal Landrio Drive
Johnstown, NY 12095
(518) 725-0209
Contact: Christopher B. Lake
Manager of RA/QA

Date Prepared:

September 16, 2002 (revised January 15, 2003)(revised May 16, 2003)

Trade Name:

Versa-Kath Epidural Catheter

Common Name:

Anesthesia Conduction Catheter

Product Class/Classification:

Class II 73 BSO

Predicate Device(s):

Racz Epidural Catheter (K954584)

Description:

The Versa-Kath Epidural Catheter consists of a stainless steel spring lumen with a dual coating. The inner coating is Polyester tube and the outer coating is Fluorinated Ethylene Polypropylene tube. A stylet is also provided with the device which consists of a stainless steel wire and a molded plastic hub.

The Versa-Kath will be provided as a sterile, single use, disposable device. The Versa-Kath will be a 21 gauge catheter available in various lengths.

Intended Use:

For administration of anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia for up to 72 hours.

Comparison to Predicate:

The Versa-Kath Epidural Catheter has similar physical and technical characteristics to the predicate device and a similar intended use to the predicate device.

Non-Clinical Data:

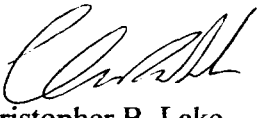
Bench Testing performed on the Versa-Kath Epidural Catheter to compare performance characteristics to the predicate device confirmed that the performance of the Versa-Kath is similar to that of the device. The devices were tested with regard to Tensile strength, Flow, and Deflection(stiffness) Conformance to BS 6196. Fluid Pressure of the catheter/adapter connection, luminal integrity were also compared to the predicate.

Conclusion:

The testing performed and comparison to the predicate device demonstrates that the Versa-Kath Epidural Catheter is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

Epimed International, Inc.



Christopher B. Lake
Manager of Quality Assurance/Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2003

Mr. Christopher B. Lake
Manager of Quality Assurance/Regulatory Affairs
Epimed International, Incorporated
141 Sal Landrio Drive
Crossroads Business Park
Johnstown, NY 12095

Re: K023140
Trade/Device Name: Versa-Kath Epidural Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: May 16, 2003
Received: May 19, 2003

Dear Mr. Lake:

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use statement

510(k) Number (if known): K023140

Device Name: Versa-Kath Epidural Catheter

Indications For Use:

For administration of anesthetic agents 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 Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K023140

(Optional Format 3-10-98)

✓ Prescription Devices