APR - 3 2003

K030562

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:

February 19, 2003

Trade Name:

Tuohy Epidural Needle

Common Name:

Epidural Needle

Product Class/Classification:

Class II
868.5150 Needle, Conduction, Anesthetic

Predicate Device(s):

Manan Medical Products Epidural Needle (K980536)

Description:

The Tuohy Epidural Needle consists of a stainless steel cannula with a ground beveled distal tip. A plastic hub is molded onto the proximal end of the cannula. A stylet is also provided with the device which consists of a stainless steel wire shaft and a molded plastic hub.

The Tuohy Epidural Needle will be provided as a sterile, single use, disposable device. The Epidural Needle will be available in a variety of lengths and gauges.

Intended Use:

The Epidural Needle is intended for the epidural placement, directly or through an epidural catheter, of anesthetic agents to elicit regional anesthesia.

Comparison to Predicate:

The Tuohy Epidural Needle has identical physical and technical characteristics to the Manan Medical Products Epidural Needle marketed under K980536.

Non-Clinical Data:

Due to the fact that this product is purchased by Epimed from Manan Medical and is identical to the predicate device, bench testing to compare performance characteristics was not conducted.

Conclusion:

The comparison to the predicate device demonstrates that the Tuohy Epidural Needle is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

Epimed International, Inc.

Christopher B. Lake
Manager of Regulatory Affairs/Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2003

Mr. Christopher B. Lake
Epimed International, Incorporated
141 Sal Landrio Drive
Crossroads Business Park
Johnstown, New York 12095

Re: K030562
Trade/Device Name: Tuohy Epidural Needles; Models A-NE-009, A-NE-012, A-NE-014, A-NE-016, A-NE-029, A-NE-056, A-NE-057, A-NE-058, A-NE-059, A-NE-060, and A-NE-061
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II (two)
Product Code: 73 BSP
Dated: February 19, 2003
Received: February 21, 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.

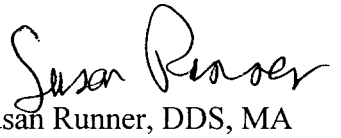
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

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

510(k) Number (if known): K030562

Device Name: Epidural Needle

Indications For Use:

The Epidural Needle is intended for the epidural placement, directly or through an epidural catheter, of anesthetic agents to elicit regional anesthesia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription use -OR- — Over-the-counter use

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030562