MAY 27 2005 K050557

XIV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Pages)

A. Submitter: Michael Renick, American Medical Technologies, 1211 West 13th St. Rivera Beach, Fl. 33404. Phone: 561-818-0625.

I. Classification Name and Number: Catheter, Conduction, Anesthetic, Class II, BSO

II. Common/Usual Name: Epidural catheter

III. Proprietary Name: AMT NanoCath™

III.1. Registration No: in process

IV. Classification: This device was classified by the U. S. Food and Drug Administration Anesthesiology Devices Panel (Title 21 Code of Federal Regulations, Part 868.5120). The FDA Classification "Number" is BSO; the product is in Class II,

V. Performance Standards: None applicable. Surgical stainless steel meets ASTM A276 and A479 for the 304 or 316 stainless steel. The coating meets USP Class VI and ISO 10993 for biocompatibility.

VI. Description: The AMT NanoCath is comprised of a tightly coiled stainless steel, covered over most of its length with polyethylene terphthalate. The tip of the catheter is welded into a smooth cover to which is welded a safety ribbon of stainless steel. A stylet of stainless with a plastic handle made of delrin or polycarbonate fits inside the catheter. The catheter is available in 19 - 21 gauge, in lengths of 30 to 90 cm. The wire coil has an outer diameter from 0.8 to 1.0 mm. The NanoCath was compared with substantially equivalent devices in fatigue tests and shown equivalent.

VI. Substantial Equivalence: The AMT NanoCath™ is substantially equivalent to the Versa-Kath Epidural Catheter cleared by Epimed in K023140, has the same use, and was subjected to similar bench testing which confirmed that the performance is equivalent, The NanoCath™ is also equivalent to the Feth-R-Cath cleared by Epimed in K981329. It is manufactured very similarly to the Perifix FX by Braun (several 510(k)s, e.g.K042488, K033952) and is equivalent to this device. The AMT NanoCath™ is substantially equivalent as well to older epidural catheters such as the Spring-Wound Epidural Catheter cleared by Micor in K991879 and the Racz Epidural Catheter cleared in K954584.

(cont'd)

The NanoCath also is manufactured very similarly to the Perifix FX by Braun (several 510(k)s, e.g. K042488, K033952) and is equivalent to this device. The AMT NanoCath™ is substantially equivalent as well to older epidural catheters such as the Spring-Wound Epidural Catheter cleared by Micor in K991879 and the Racz Epidural Catheter cleared in K954584.

Characteristics of the materials used in the AMT NanoCath™ and in many of the current substantially equivalent devices are shown in Appendix IV.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to administer anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia for up to 72 hours.

2. The technological characteristics for this product are similar to those for the predicate devices and those currently on the market which have some differences in technology but the technological differences are well understood in the anesthetic industry so substantial equivalence in safety and effectiveness is assured.

3. The materials from which this device is made are well-established in the industry and are used in predicate devices.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment V.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Mr. Michael Renick
President
American Medical Technologies, Incorporated
1211 West 13th Street
Riviera Beach, Florida 33404

Re: K050557
Trade/Device Name: AMT NanoCath™
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: February 12, 2005
Received: March 3, 2005

Dear Mr. Renick:

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.

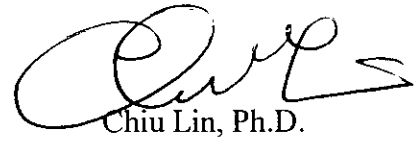
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IX. Indications for Use

510(k) Number (if known): K050557

Device Name: AMT NanoCath™

Indications For Use:

The AMT NanoCath™ epidural catheter is intended for administration of local anesthetics into the epidural space to provide continuous epidural caudal anesthesia for up to 72 hours

Prescription Use __X___ (Per 21 CFR 801.109) OR Over-The-Counter Use____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Evaluation (ODE)

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

510(k) Number K050557