K991879

OCT 28 1999

Summary of Safety and Effectiveness

MICOR®, INC.
Spring-Wound Epidural Catheter

1.0 Micor Contact

Charles W. Eslep
Vice President
Micor, Inc.
2855 Oxford Boulevard
Allison Park, Pennsylvania 15101
Telephone: (412)487-1113
Facsimile: (412)487-1747

2.0 Device Name

2.1 Trade Name

Spring-Wound Epidural Catheter

2.2 Classification Name

Device Name:	Catheter, Conduction, Anesthetic
Speciality:	Anesthesiology
Product Code:	73 BSO
Device Class:	2
Regulation No.:	21 CFR 868.5120

3.0 Predicate Device

3.1 Arrow International, Inc. *FlexTip Plus*® Epidural Catheter

3.2 Epimed International, Inc. *Feth-R-Kath*® Epidural Catheters (K981329)

3.3 Preferred Medical Products Epidural Catheter (K885278)

4.0 Product Description/Function

4.1 **Description** This catheter exhibits the same design and performance characteristics as the Arrow and Epimed predicates. Its external sheath (patient-contact) material is identical to that used in the Preferred Medical predicate.

4.2 **Function** The subject device will function the same as the predicate devices.

5.0 Comparison of the Subject Device and Predicate Devices for Equivalence

5.1 **General** Catheters incorporating an internal spiral-wound spring, and being used for the delivery of anesthetic agents, have been on the U.S. market for over 10 years. These include catheters built and legally-marketed by Arrow International and Epimed International.

5.2 **Technological Characteristics** The technological characteristics of Micor's Spring-Wound Epidural Catheter, as compared to those of the Arrow and Epimed predicates, are essentially the same.

5.3 **Materials** The materials incorporated in the subject device are identical to ones contained in the legally-marketed predicates, Arrow's *FlexTip Plus*, Epimed's *Feth-R-Cath*, and Preferred Medical's epidural catheter.

5.4 **Intended Use** The intended use of the subject device is equivalent to that of all three predicate devices.

5.5 **Conclusion** No new issues of safety or effectiveness are raised by the design of this device. Micor's Spring-Wound Epidural Catheter is equivalent to the cited predicate devices in its material, technology, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1999

Mr. Charles W. Eslep
Micor, Inc.
2855 Oxford Boulevard
Allison Park, PA 15101

Re: K991879
Micor Spring Wound Catheter (part# CS **-0217)
Regulatory Class: II (twc)
Product Code: 73 BSO
Dated: September 23, 1999
Received: September 28, 1999

Dear Mr. Eslep:

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,

Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K991879

510(k) Number (if known)

Spring-Wound Epidural Catheter

Device Name

Indications for Use:

The *Spring-Wound Epidiral Catheter* is intended for administration of local anesthetic agents into the epidural space to provide continuous epidural or caudal anesthesia. Micor recommends that the catheter be removed or replaced every 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 K991879

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