K983125

NOV 17 1998

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Mr. James R. Whitney
Group Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-8211
E-Mail: 73451.1040@compuserve.com

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Anesthesia Conduction Kit

Common Name: Epidural Catheter Kit

Proprietary Name: Epidural Catheter and accessories

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Epidural Catheter and accessories is substantially equivalent to the Aries (K840201).

4. Description of the Device.

The Epidural Catheter and accessories consists of an epidural, a stylet, a threading aid and a connector. The components are packaged in a tray. The tray is placed

in a paperboard box with an outer box.

5. **Intended Use of the Device.**

The Epidural Catheter and accessories is a product used to administer to a patient conduction, regional, or local anesthesia.

6. **Summary of Technological Characteristics.**

The technological characteristics are the same as, or equivalent to, predicate devices in design use and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 1998

Mr. James R. Whitney
Group Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K983125
Epidural Catheter Models 1210/1200
Regulatory Class: II (two)
Product Code: 73 CAZ
Dated: September 1, 1998
Received: September 8, 1998

Dear Mr. Whitney:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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,

for 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): K983125

Device Name: Epidural Catheter and accessories

Indications for Use:

To administer to a patient conduction, regional, or local anesthesia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983125

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)