K992471

SMITHS INDUSTRIES
Medical Systems

OCT 22 1999

SIMS Portex Inc.
10 Bowman Drive
PO Box 0724
Keene NH 03431 USA
Telephone: 603-352-3812
Fax: 603-352-3703

H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

SIMS Portex Inc
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Timothy J. Talcott
Manager, Regulatory Affairs

PREPARATION DATE OF SUMMARY:

July 23, 1999

TRADE NAME:

SIMS Portex Epidural Catheter

COMMON NAME:

Anesthesia Conduction Catheter

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 BSO, 21 CFR 868.5120

PREDICATE DEVICE(S):

SIMS Portex Inc. epidural catheters;
4910-16/17, 20g nylon, closed-end, three-eyed
4910-18, 21g nylon, closed-end, three-eyed

These devices are marketed as **'Preamendment'**.

DESCRIPTION:

The SIMS Portex Epidural Catheter is made of flexible, nylon tubing. The catheter may be closed-ended with lateral eyes or an open-ended catheter with finished tip. The tip of the catheter is marked. The catheter has a single mark at 5 cm from the tip with 1 cm increments, up to 20 cm. The 10 cm mark is indicated by two marks, 15 cm by three marks, and 20 cm by four marks.

The catheter is available in 20g (O.D. .042"/I.D. .023") or 21g (O.D. .033"/I.D. .019") sizes. The catheters have a nominal length of 38 inches. The catheters may include a stylete.

The catheters are provided with a catheter connector (K965017) to provide a means of administration of anesthetics and/or analgesics. They are provided sterile in individual packages or as a component of a continuous epidural procedure tray (K965017).

INDICATIONS FOR USE:

The SIMS Portex Epidural Catheter is indicated for the injection of local anesthetics into the epidural space.

TECHNICAL CHARACTERISTICS:

The design of the catheter is identical to the predicate device, accept for the change in material. This change in material has no affect on performance criteria, accept an increase in percent elongation.

NON-CLINICAL DATA:

Data submitted demonstrates that the epidural catheter performs equivalently to the predicate device. Data submitted covers; dimensional characteristics, flow rate, compression resistance, hub/catheter detachment, defection resistance modulus of elasticity, tensile strength, elongation, ETO residuals, and biological safety per ISO 10993.

CLINICAL DATA:

Not applicable

CONCLUSION:

The comparison to the predicate devices demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

SIMS PORTEX INC.

Timothy J. Talcott
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

Mr. Timothy J. Talcott
SIMS Portex Inc.
10 Bowman Drive
Keene, NH 03431

Re: K992471
Epidural Catheter
Regulatory Class: II (two)
Product Code: 73 BSO
Dated: July 23, 1999
Received: July 26, 1999

Dear Mr. Talcott:

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,

Jean A Welsh for,

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

Enclosure

B: INTENDED USE OF DEVICE

PROPOSED INDICATIONS FOR USE:

510(k) Number (if known): Unknown

Device Name: Epidural Catheter

Indications For Use:

The SIMS Portex Epidural Catheter is indicated for the injection of local anesthetics into the epidural space.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992471