SIMS SMITHS INDUSTRIES
Medical Systems

K994275

FEB 22 2000

SIMS Portex Inc.
10 Bowman Drive
PO Box 0724
Keene NH 03431 USA
Telephone: 603-352-3812
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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
Director of Regulatory Compliance

PREPARATION DATE OF SUMMARY:

February 16, 2000

TRADE NAME:

SIMS Portex Anesthesia Catheter

COMMON NAME:

Anesthesia Conduction Catheter

PRODUCT CLASS/CLASSIFICATION:

Class II, 79 MEB, accessory to 21 CFR 880.5725 (infusion pump)

PREDICATE DEVICE(S):

SIMS Portex Inc., Epidural Catheter;
4910-18, 21g nylon, closed-end, three-eyed
This device is marketed under 510(k), K992471.

B. Braun Medical Inc., PERIFIX® Epidural Catheter Set, EC20-C
This device is marketed under 510(k), K813186 and the indications for use are as specified in I-Flow Corporation's 510(k)s, K980558 and K991543.

DESCRIPTION:

The SIMS Portex Anesthesia 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 as 21g (O.D. .033"/I.D. .019"). 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, analgesics, and/or narcotics. The catheter may be used in conjunction with an infusion pump. The catheter may be used, outside of the epidural space, for up to 30 days. An insertion device may be provided to aid the placement of the catheter into the introducer needle. They are provided sterile in individual packages or as a component of a regional anesthesia procedure tray (K965017).

INDICATIONS FOR USE:

The SIMS Portex Anesthesia Catheter is indicated for the infusion of local anesthetics or narcotics into the intraoperative site for post operative pain management and for regional anesthesia, outside of the epidural space. Routes of administration may include intraoperative or percutaneous. The catheter is not intended for intravenous or intramuscular use.

TECHNICAL CHARACTERISTICS:

The design of the catheter and materials are identical to our current catheter. The catheter has been evaluated and demonstrated equivalency to the predicate devices for the following dimensional and functional characteristics: ID, OD, length, flow rate, leakage, eye patency, tensile strength, percentage elongation, luer taper, and security of connection of the catheter to the catheter connector.

NON-CLINICAL DATA:

Data submitted demonstrates that the catheter performs equivalently to the predicate devices. Data submitted covers; dimensional characteristics, flow rate, leakage, hub/catheter detachment, 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
Director of Regulatory Compliance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2000

Mr. Timothy J. Talcott
Manager, Regulatory Affairs
SIMS Portex, Incorporated
10 Bowman Drive
P.O. Box 0724
Keene, New Hamphshire 03431

Re: K994275
Trade Name: SIMS Portex Anesthesia Catheter
Regulatory Class: II
Product Code: FRN
Dated: December 17, 1999
Received: December 20, 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

wmB

510(k) Number (if known): ~~Unknown~~ K994275

Device Name: Anesthesia Catheter

Indications For Use:

The SIMS Portex Anesthesia Catheter is indicated for the infusion of local anesthetics or narcotics into the intraoperative site for post operative pain management and for regional anesthesia, outside of the epidural space. Routes of administration may include intraoperative or percutaneous. The catheter is not intended for intravenous or intramuscular use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K994275