SMITHS INDUSTRIES
Medical Systems

K983858

JAN 29 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:

October 30, 1998

TRADE NAME:

Spinal Anesthesia Needles

COMMON NAME:

Spinal Anesthesia Needles

PRODUCT CLASS/CLASSIFICATION:

Class II, 80 MIA, 21 CFR 862.5150

PREDICATE DEVICE(S):

Becton-Dickinson spinal needles, marketed as preamendment devices.
Pajunk Medizintechnologie, Germany, Sprotte spinal needles, marketed under 510(k) K911221 and K911202.
Preferred Medical Products (a division of Ballard Medical Products), spinal needles purchased from Unisis Corp., Tokyo, Japan, marketed under K885277.
Sherwood Medical, introducer needle, marketed as preamendment device.
American Medical Instruments, Inc., New Bedford, MA, introducer needles, marketed as preamendment devices.

DESCRIPTION:

A spinal needle is an instrument used for the injection of local anesthetics into a patient to provide regional anesthesia. The needle consists of a luer hub, a stainless steel cannula, and a stainless steel stylete. The needles are provided as sterile, single use, disposable devices. They may be packaged individually or included in our regional anesthesia trays. The spinal needles are provided in three styles; Lancet Point (Quincke), Pencil Point (Whitacre), and European Style (Sprotte) (refer to drawings, attachment IX). The needles range in size as indicated in the following table:

Needle Style	Gage Size Range	Length Range
Lancet Point	18g to 25g	2.0" to 6.0"
Pencil Point	22g to 25g	2.0" to 6.0"
European Style	24g to 25g	2.0" to 6.0"

The introducer needle is a simple hypodermic needle, either 18g or 20g, to make the initial puncture through the skin to aid in the placement of the spinal needle.

INDICATIONS FOR USE:

Spinal needles are indicated for the injection of local anesthetics into a patient to provide regional anesthesia.

TECHNICAL CHARACTERISTICS:

The device has the same technical characteristics as the predicate device marketed by Preferred Medical Products, Becton-Dickinson, Pajunk, Sherwood, and AMI.

NON-CLINICAL DATA:

To summarize, comparison testing between the proposed device and the predicate devices from Becton Dickinson, Pajunk, Sherwood, and AMI, the proposed devices compared well against the predicate devices. For the spinal needles, overall, an increased inside diameter

was achieved with a reduced outside diameter and wall thickness, while still achieving increased strength of the cannula.

The greater inside diameter allowed for an increased flow rate for all of the Unisis needles tested. The flashback in the European Style (Sprotte) needles was generally quicker for the proposed device. The results of the Quincke (K-3 Lancet) type needles showed similar results for the 18, 20, and 22-gage cannula. The 25-gage cannula showed an improved rate of flashback. The Whitacre (Pencil Point) type needles also showed similar results between the predicate and proposed devices. When the stylete is retracted, the rate of flashback will be further increased.

Finally, the penetration force for all proposed needles was reduced by as much as 32.8% for the Whitacre (Pencil Point) type needle, except for the 22g and 25g Quincke (K-3 Lancet) type needle, 1.9% and 13.3% respectively.

There are three proposed introducer needles. These compare favorably to the Sherwood and AMI needles for all criteria.

In summary, the differences in these needles are not significant and substantiate that the needles are safe and effective. This testing, and the marketing of the same spinal needles by Preferred Medical Products, substantiates this claim.

CONCLUSION:

The testing performed and comparison to the predicate devices demonstrate that the proposed devices are safe and effective and are 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

JAN 29 1999

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

Re: K983858
Spinal Anesthesia Needles and Introducer Needles
Regulatory Class: II (two)
Product Code: MIA
Dated: October 30, 1998
Received: November 2, 1998

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" (21CFR 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
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: Spinal Anesthesia Needles

Indications For Use:

Spinal needles are indicated for the injection of local anesthetics into a patient to provide regional anesthesia.

(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_____

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983858