SMITHS INDUSTRIES
Medical Systems

K993619

APR 2 8 2000

SIMS Portex Inc.

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# 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 22, 1999

## TRADE NAME:

CSEcure™ Combined Spinal/Epidural Anesthesia System with Lock

## COMMON NAME:

Combined Spinal/Epidural Anesthesia Needle

## PRODUCT CLASS/CLASSIFICATION:

Class II, 80 MIA, 21 CFR 862.5150

## PREDICATE DEVICE(S):

Becton-Dickinson Durasafe™ Combined Spinal/Epidural Anesthesia Needle Set, K932249.

## DESCRIPTION:

Combined Spinal/Epidural Anesthesia Needles are instruments used for a spinal (subarachnoid) injection of anesthetics, followed by the placement of an epidural catheter to allow modification of the spinal analgesia if necessary, or bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space for subsequent pain relief if required. The spinal needle consists of a luer hub, a stainless steel cannula with a pencil point tip, a stainless steel stylete, and a locking colar. The tuohy epidural needle consists of a luer hub, a stainless steel cannula with a Weiss tip, and a matching flange to accept the spinal needles locking colar. The needles are a matched set. The needles are provided as sterile, single use, disposable devices. They may be packaged as a set or included as a set in our regional anesthesia trays. The sizes are tabulated below:

| | Spinal Needle | |
|---|---|---|
| | 26g 5 3/16" (132 mm) | 27g 5 3/16" (132 mm) |
| Epidural Needle | | |
| 17g 3.5" (90 mm) | X | X |
| 18g 3.5" (90 mm) | | X |

The Tuohy needle and the spinal needle have interlocking collars that enable the spinal needle to be locked into position once the dura has been pierced so that it is secured to the Tuohy needle to prevent acceidental displacement. The numbers on the Tuohy needle hub indicate the distance in millimeters that the spinal needle protrudes from the epidural Tuohy needle.

## INDICATIONS FOR USE:

The Combined Spinal/Epidural Anesthesia System is indicated for the injections of local anesthetics into the spinal and epidural spaces of a patient to provide regional anesthesia. The adminsistration of the spinal anesthesia allows rapid anesthesia onset and the placement of an epidural catheter allows for bolus injections or continuous infusion of local anesthetics or other drugs into the epidural space.

## TECHNICAL CHARACTERISTICS:

The device has the same technical characteristics as the predicate device marketed by Becton-Dickinson.

## NON-CLINICAL DATA:

To summarize, comparison testing between the proposed device and the predicate device from Becton Dickinson compared well. There were no differences seen in performance accept for an increased flow rate of 28.6% in the 27g spinal needle. The differences in these needles are not significant and substantiate that the needles are safe and effective. The testing substantiates this claim.

**CONCLUSION:**

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

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

APR 2 8 2000

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

Re: K993619
CSEcure™ Combined Spinal/Epidural Anesthesia System with Lock
Regulatory Class: II (two)
Product Code: 73 BSP
Dated: February 17, 2000
Received: February 22, 2000

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown K993619

Device Name: CSEcure™ Combined Spinal/Epidural Anesthesia System with Lock

Indications For Use:

The combined spinal epidural needle kit is intended for injection of local anesthetics into the intrathecal space via a spinal needle introduced through the epidural needle, and injection of local anesthetics into the epidural space via the epidural needle, or via an epidural catheter passed through the epidural needle.

(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 K993619