SMITHS INDUSTRIES
Medical Systems

K01 1925

JUL 1 2 2001

SIMS Portex Inc.

10 Bowman Drive
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Keene NH 03431 USA
Telephone: 603-352-3812
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K: 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: Brian D. Farias
Regulatory Affairs Specialist

PREPARATION DATE OF SUMMARY:

June 19, 2001

TRADE NAME:

Hypodermic Needle-Pro® Needle with Needle Protection Device
Hypodermic Needle-Pro® Syringe & Needle with Needle Protection Device

COMMON NAME:

Hypodermic Needle and Syringe with attached needle protection

PRODUCT CLASS/CLASSIFICATION:

Class II, 80 FMI, 21 CFR 880.5570 (Hypodermic Single Lumen Needles)
This filing is under FMI as the needle protection device is attached to the needle.

PREDICATE DEVICE(S):

K923127 Needle-Pro™ Cartridge

DESCRIPTION:

This device is intended for injection or aspiration of fluids utilizing a luer slip syringe. The needle protection device is an integral component of the device as it comes pre-attached to the needle. Once the needle/needle protection device is attached to a syringe, the collar hoop hinders removal of the needle protection device from the needle. The Needle-Pro® sheath may be adjusted relative to the needle bevel by swiveling the orange arm to the desired position. After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. As the needle enters the protective sheath, the needle protection device engages and the needle is contained within the sheath. The device should be immediately be disposed into a sharps container. This device is not designed for use with a luer lock syringe. The device is supplied with 25G, 26G, 27G needles both with and without a syringe.

INDICATIONS FOR USE:

This device is intended for injection or aspiration of fluids utilizing a luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks. The Needle-Pro® device is not designed for use with a luer lock syringe.

TECHNICAL CHARACTERISTICS:

The proposed device is composed of the same components and materials as the predicate devices. The device is sold sterile.

NON-CLINICAL DATA:

The bench test data submitted demonstrates that the proposed device has an equal or greater ability to resist static and dynamic forces, as compared to the predicate devices, while testing for needle disengagement.

CLINICAL DATA:

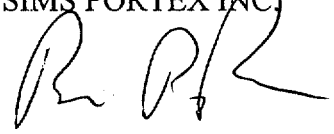
Not applicable

CONCLUSION:

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

Very truly yours,

SIMS PORTEX INC.



Brian D. Farias
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Mr. Brain D. Farias
Regulatory Affairs Specialist
Sims Portex, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K011925
Trade/Device Name: Hypodermic Needles-Pro® Needle with Needle Protection Device and Hypodermic Needle-Pro® Syringe and Needle Potection Device Needles
Regulation Number: 880.5570
Regulatory Class: II
Product Code: FMI
Dated: June 19, 2001
Received: June 20, 2001

Dear Mr Farias:

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) 594-4692. 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" (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,

Susan Runner

for Timothy A. Ulatowski
Directorrrr
Division of Dental, Infection Control
and General Hospital 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:
Hypodermic Needle-Pro® Needle with Needle Protection Device
Hypodermic Needle-Pro® Syringe & Needle with Needle Protection Device

Indications For Use:

This device is intended for injection or aspiration of fluids utilizing a luer slip syringe. The needle protection device covers the needle after use to help prevent needle sticks. The Needle-Pro® device is not designed for use with a luer lock syringe.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K01 1925