K981035

SMITHS INDUSTRIES
Medical Systems

SIMS Portex Inc.
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J: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 21 1998

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:

March 13, 1998

TRADE NAME:

Pro-Vent® and Pulsator® Arterial Blood Sampling Syringes

COMMON NAME:

Arterial Blood Sampling Syringes

PRODUCT CLASS/CLASSIFICATION:

Class II, 75 GJE, 21 CFR 862.1675.

PREDICATE DEVICE(S):

Our Arterial Blood Sampling syringes with Calcium Neutralized Dry Lithium Heparin (K952516).

DESCRIPTION:

A commercially available hypodermic needle is modified by dispensing sodium heparin into the hub and cannula and then drying the heparin. The total recoverable volume of the heparin is approximately 5 U.S.P. units. The needle is then attached to a Pro-Vent® or Pulsator® Arterial Blood Sampling Syringe, which contains approximately 25 U.S.P. units of Calcium Neutralized Dry Lithium Heparin. The device is packaged and sterilized by Ethylene Oxide.

INDICATIONS FOR USE:

The arterial blood sampling syringe is intended for sampling of arterial blood for the measurement of pO_2, pCO_2, pH, CO-oximetry, electrolytes (Ca^{++}, Na^+, K^+, Cl^-, and Mg^{++}), Total Magnesium, and the metabolites (Glucose and Lactate).

TECHNICAL CHARACTERISTICS:

The proposed syringe with heparinized needle has dry calcium neutralized lithium heparin in the syringe and dried sodium heparin in the needle. Calcium Neutralized Dry Lithium Heparin is used in our Arterial Blood Gas Sampling Syringes, currently legally marketed (K952516). Sodium Heparin is used in our liquid filled Arterial Blood Gas Sampling Syringes, currently marketed (K952516). Materials of the syringe and needle are unchanged from our current Arterial Blood Gas Sampling Syringes. Sterilization is by the same methods employed in our existing Arterial Blood Gas Sampling Syringes, as authorized by FDA in 510(k) K952516.

NON-CLINICAL DATA:

The proposed syringes were tested in a side-by-side comparison to our current Arterial Blood Sampling Syringes with Calcium Neutralized Dry Lithium Heparin. The testing consisted of the sampling of arterial blood and the subsequent measurement of pO_2, pCO_2, pH, CO-oximetry, Ca^{++}, Mg^{++}, Na^+, K^+, Cl^-, Total Magnesium, Glucose, and Lactate. The results of the measurements were compared. There was no statistical difference between the proposed syringes and the predicate device.

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
dba Concord/Portex

Timothy J. Talcott
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 21 1998

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

Re: K981035
Pro-Vent® and Pulsator® Arterial Blood Sampling Syringes
Regulatory Class: II
Product Code: JKA
Dated: March 13, 1998
Received: March 19, 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 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B: INTENDED USE OF DEVICE

PROPOSED INDICATIONS FOR USE:

The arterial blood sampling syringe is intended for sampling of arterial blood for the measurement of pO_2, pCO_2, pH, CO-oximetry, electrolytes (Ca^{++}, Na^+, K^+, Cl^-, and Mg^{++}), Total Magnesium, and the metabolites (Glucose and Lactate).

Patricia Bernhardt (for A. Montgomery)
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981035

prescription use ✓