



**SMITHS INDUSTRIES**

*Medical Systems*

SIMS Inc.

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**H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**510(K) SUMMARY**

**COMPANY INFORMATION**

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Contact: Timothy J. Talcott

Manager, Regulatory Affairs

**PREPARATION DATE OF SUMMARY**

July 26, 1996

**TRADE NAME**

SIMS Pro-Vent® 250 (500) Plus

**COMMON NAME**

Arterial Blood Sampling Kit

**CLASSIFICATION NAME**

Class II, 75 GJE, 21 CFR 862.1675

## **PREDICATE DEVICE**

SIMS Pro-Vent® Arterial Blood Sampling Kit with Calcium Neutralized Dry Lithium Heparin.

AVL Scientific Corporation's Microsampler Arterial Blood Gas Kit, 240µl and 500µl.

## **DESCRIPTION**

The SIMS Pro-Vent® 250 (500) Plus contains a precision small volume sampling device for obtaining an arterial blood sample. The device consists of a small gauge needle (25g) attached to a single cannula vented tube with a micro volume of 250µl or 500µl (.25 or .50cc). The SIMS Pro-Vent® 250 (500) Plus is ideal for obtaining blood samples from pediatric, neonatal and geriatric patients. Each device contains approximately 40 units of Calcium Neutralized Dry Lithium Heparin per ml. The 250µl device contains approximately 10 U.S.P. units of heparin and the 500µl device contains approximately 20 U.S.P. units of heparin.

## **INDICATIONS FOR USE**

The SIMS Pro-Vent® 250 (500) Plus is intended for obtaining small volume samples of blood for the measurement of pH, pO<sub>2</sub>, pCO<sub>2</sub>, CO-oximetry, electrolytes (Ca<sup>++</sup>, Mg<sup>++</sup>, Na<sup>+</sup>, Cl<sup>-</sup>, K<sup>+</sup>) and the metabolites (Glucose and Lactate).

## **TECHNOLOGICAL CHARACTERISTICS**

The proposed device has a calcium neutralized lithium heparin. Calcium Neutralized Dry Lithium Heparin is used in our Arterial Blood Gas Sampling Syringes, currently legally marketed (K952516). The proposed device draws a blood sample dependent on the arterial pressure in a similar manner as AVL Scientific Corporation's Microsampler Arterial Blood Gas Kit, 240µl and 500µl. Sterilization is by the same methods employed in our existing Arterial Blood Gas Sampling Kit.

## **SUMMARY OF PERFORMANCE DATA**

The proposed device was compared to AVL Scientific Corporation's Microsampler Arterial Blood Gas Kit, 240µl and 500µl, for fill time since both devices rely on arterial pressure for obtaining the sample. The results demonstrate that the proposed device fills under lower pressure and in less time than the predicate device.

#### SUMMARY OF NONCLINICAL AND CLINICAL TESTS

The proposed device was tested in a side-by-side comparison to the SIMS Pro-Vent® Arterial Blood Sampling Kit with Calcium Neutralized Dry Lithium Heparin. The testing consisted of the sampling of arterial blood and the subsequent measurement of pO<sub>2</sub>, pCO<sub>2</sub>, pH, Ca<sup>++</sup>, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, and Glucose. The results of the measurements were compared. There was no statistical difference between the proposed device and the predicate device. There was no drift in the measurement of CO-oximetry when compared to the baseline for the blood sampled.

#### CONCLUSION OF NONCLINICAL AND CLINICAL TESTS

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

#### ADDITIONAL INFORMATION

None

Very truly yours,

Smiths Industries Medical Systems, Inc.  
dba Concord/Portex

A handwritten signature in black ink, appearing to read "Timothy J. Talcott", with a long horizontal flourish extending to the right.

Timothy J. Talcott  
Manager, Regulatory Affairs