

II.**510k SUMMARY**

FEB 5 1999

BIOPORT Closed Blood Sampling System
Prepared August 21, 1998

1. Submitted by

John Shulze
Sunscope International, Inc.
20250 Acacia St., Suite 115
Newport Beach, CA 92660
Tel: (949) 553-8300
Fax: (949) 553-9129

2. Contact Person

John Shulze

3. Device Identification

Trade Name	BIOPORT System
Common Name	Arterial Blood Access System
Classification Name	Continuous Flush Catheter

4. Predicate Device(s)

Utah Medical Products Inc.'s ABC Pressure Monitoring Kits; Baxter Healthcare Corporation's VAMP Venous/Arterial Blood Management Protection; Migada Blunt Cannula.

5. Device Description

The BIOPORT System is composed of a 3-way stopcock; BIOPORT (a pre-slit latex rubber septum housed in a clear, rigid, plastic housing); a 3 cc Reservoir Syringe with protective dust cover over the plunger shaft to minimize contamination of Syringe contents by dust particles; and high-pressure Extension Tubing. The BIOPORT and stopcock are bonded 12 and 14 inches, respectively, from the distal male Luer lock connector of the pressure monitoring tubing. The 3-cc Luer lock Reservoir Syringe is pre-attached to the 3-way stopcock. The stopcock, BIOPORT, and Reservoir Syringe are located on a rigid plastic support equipped with a Velcro-type fastener for mounting on a patient's arm.

A Blunt Cannula Adapter (BPN)- terminating in a female Luer lock connector at one end for attachment to the male Luer of a sampling syringe, and a hollow, blunt plastic cone at the other end for insertion into the pre-slit septum of the BIOPORT- is provided separately to effect needle-free blood access via the BIOPORT.

6. Intended Use

BIOPORT Systems are designed for closed, needle-free access of arterial blood from pressure monitoring catheters.

The BIOPORT System is designed for needle-free access of undiluted blood from arterial catheters not longer than 6.4 cm (2 - ½ "). Diluted, heparinized blood is drawn beyond the BIOPORT into the BPS Reservoir Syringe to permit needle-free withdrawal of undiluted blood from the BIOPORT using a sampling syringe fitted with the Blunt Cannula Adapter (BPN). After the undiluted sample is drawn, the diluted, heparinized blood in the Reservoir Syringe is reinfused into the patient to reduce fluid loss.

7. Summary of Technological Characteristics of Device in relation to Predicate Device(s)

The configuration of the BIOPORT System with attached Reservoir Syringe is similar to that of the predicate arm-mounted VAMP (K885281). Heparinized, diluted blood is drawn into the VAMP reservoir to clear the BIOPORT and distal volume in the VAMP. It is drawn into BIOPORT's Reservoir Syringe to clear heparinized, diluted blood from the BIOPORT and volume distal to the BIOPORT in the BIOPORT System. In both systems the heparinized, diluted blood is returned to the patient.

8. Assessment of Performance Data used to justify Substantial Equivalence Claim

All components meet ISO 10993 and FDA's G95-1 Memorandum biocompatibility requirements.

Performance data demonstrate that the tensile strength and resistance to leakage under pressure of the BIOPORT System components (all components bonded to tubing and the tubing itself) meet or exceed the requirements listed in International Standard ISO 8536-4 Infusion equipment for medical use- Part 4: Infusion sets for single use. This document is now accepted by the FDA as a Consensus Standard.

The frequency response (bandwidth) of the BIOTRANS Reusable Sensor Base with the BIOPORT sampling site present in the fluid pathway was evaluated in accordance with BP 22, American National Standard for Blood Pressure Transducers. The bandwidth was found to be acceptable (>200 Hz).

The identical BIOPORT access site and Blunt Cannula Adapter are used in the predicate Utah Medical Products' ABC and have been cleared for identical purposes.

Tests of the Reservoir Syringes at hydrostatic pressures anticipated in the use of the device demonstrate the adequacy of the stop at the rear of the syringe barrel to minimize the potential for inadvertent expulsion of the plunger.

9. Conclusion

Data gathered by Biosensors indicate that the performance of Biosensors BIOPORT System is equivalent to that of the predicate devices or meets the requirements of applicable, published, well-accepted standards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 1999

Phil Triolo, Ph.D.
Principal
C/O PT Consulting
Sunscope International, Inc.
148 So. 1200 East
Salt Lake City, UT 84102

Re: K983372
Trade Name: BIOPORT System
Regulatory Class: II
Product Code: DRS
Dated: December 21, 1998
Received: December 22, 1998

Dear Dr. Triolo:

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

Page 2 - Dr. Phil Triolo

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) 594-4586. 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, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) K 983372

Device Name Biosensors Internationals' BIOPORT Closed Blood Sampling System

Indications for Use

The BIOPORT System is designed for closed, needle-free access of arterial blood from pressure monitoring catheters.

The BIOPORT System is designed for needle-free access of undiluted blood from arterial catheters (typically 16 or 18 Ga.) not longer than 6.4 cm (2 - 1/2 "). Diluted, heparinized blood is drawn beyond the BIOPORT into the BPS Reservoir Syringe to permit needle-free withdrawal of undiluted blood from the BIOPORT using a blood sampling syringe fitted with the Blunt Cannula Adapter (BPN). After the undiluted sample is drawn, the heparinized, diluted blood in the Reservoir Syringe is reinfused into the patient to reduce fluid loss.

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K983372

Prescription Use (Per 21 CFR 801.109)

OR

Over-the Counter Use _____

(Optional Format 1-2-96)