II. JUL 17 1998

510K SUMMARY
Prepared April 28, 1998

K981745

1. Submitted by:

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2. Contact Person:
John Shulze

3. Device Identification:

Trade Name:	BIOTRANS Reusable Sensor Base
Common Name:	Physiologic Pressure Transducer
Classification Name:	Transducer, Blood Pressure, Extravascular

4. Predicate Device(s):
Medex Inc.'s (Medex's) MX 860 Novatrans II reusable pressure transducer (K951129) and MX 960 (K961404), and Utah Medical Products, Inc.'s Monitoring Cables (K841788).

5. Device Description:
The BIOTRANS Pressure Monitoring System consists of the sterile, single-use BIOTRANS Pressure Monitoring Kit (subject of a separate 510k) and BIOTRANS Reusable Sensor Base and Monitor Adapter Cables. The Base consists of a rugged silicon-based piezoresistive pressure sensor mounted on a rigid plastic support. A standard Wheatstone Bridge circuit etched into the sensor is used to detect pressure changes applied to the sensor and convert them to electronic signals for display on standard monitoring equipment.

The sensor is electrically isolated from the patient by a dielectric gel and two elastomeric diaphragms. The physiologic pressure waveform is conveyed from the patient catheter via a fluid-filled pathway to the single-use dome diaphragm. The dome diaphragm is mechanically coupled to the reusable pressure sensor diaphragm for pressure monitoring. The diaphragms make intimate contact during use permitting transfer of the pressure waveform to the transducer, with fluid contact occurring on the patient side of the disposable dome diaphragm. A 25 cm (10") Sensor cable permanently wired to the sensor transmits the electronic signal from the transducer to the patient monitor via the appropriate Monitor Adapter Cable.

The integral Sensor cables terminate in 5 different electrical adapters compatible with 5 common brands of Monitor Cables (Utah Medical, Baxter International, Medex, Abbott, and Ohmeda.) Monitor Adapter Cables designed for specific use with all major monitor suppliers are available from BSI.

The Base features built-in organizer/mounting systems compatible with standard manifold clamps for pole-mount applications.

6. **Intended Use:**
The BSI BIOTRANS is used to convert hemodynamic pressure waveforms into electrical signals which can be displayed using separate monitoring equipment. As such, its Indications for Use are identical to those for Medex's MX 860 and MX 960. BIOTRANS cables are used to make an electrical connection between the sensor and monitor. Their use is identical to that of cables manufactured by Utah Medical Products, Inc.

7. **Summary of Technological Characteristics of Device in relation to Predicate Device(s):**
The electronic design of the BSI BIOTRANS is functionally identical to that of the predicate devices. Both the BSI BIOTRANS Sensors and predicate devices employ a piezoresistive Wheatstone bridge circuit to convert physiologic pressure waveforms to an electrical signal for monitoring purposes. BIOTRANS and predicate sensors and cables devices have been shown to meet the American National Standard for Blood Pressure Transducers, ANSI/AAMI BP22-1994.

The BIOTRANS Pressure Monitoring System employs a snap fit to secure the single-use dome to the reusable sensor base, assuring intimate mechanical contact of the dome diaphragm with the sensor diaphragm. The predicate device incorporates a bayonet mechanism to secure the dome to the base. The snap fit configuration meets all electrical requirements listed in the ANSI/AAMI BP22-1994 standard.

8. **Assessment of Performance Data used to justify Substantial Equivalence Claim**
BSI's BIOTRANS meets, or exceeds, the performance requirements indicated in the American Standard for Blood Pressure Transducers, ANSI/AAMI BP22-1994. The requirements of this standard were likewise met by the predicate devices.

9. **Conclusion:**
Based on the test data gathered, Biosensors BIOTRANS Reusable Sensor Bases and Cables are substantially equivalent to Medex's reusable blood pressure transducers, Cat. No. MX 860 and MX 960, and Utah Medical Products Monitor Cables, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

Mr. John E. Shulze
Sunscope International, Inc.
20250 Acacia Street, Suite 115
Newport Beach, CA 92660

Re: K981745
BIOTRANS™ Reusable Sensor Base and Monitor Adapter Cables
Regulatory Class: II (two)
Product Code: 74 DRS
Dated: May 15, 1998
Received: May 18, 1998

Dear Mr. Shulze:

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,

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): K98174

Device Name: BIOTRANS REUSABLE SENSOR BASE

Indications For Use:

The BSI BIOTRANS Sensor Base is used to convert hemodynamic pressure waveforms via a piezoresistive bridge circuit into electrical signals which can be displayed using separate monitoring equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981745

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)