AUG 20 1998

II. 510k Summary
BIOTRANS Pressure Monitoring Kits
Prepared May 4, 1998

K981747

1. **Submitted by**

John Shulze
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2. **Contact Person**

John Shulze

3. **Device Identification:**

Trade Name	BIOTRANS Pressure Monitoring Kits
Common Name	Physiologic Pressure Monitoring Kits
Classification Name	Transducer, Blood Pressure, Extravascular

4. **Predicate Device(s)**

Medex, Inc.'s Medex MX-960, Medex MX-860; Utah Medical Products Inc.'s Pressure Monitoring Kits; Ohmeda's DTX Disposable Transducer Kits.

5. **Device Description**

The BIOTRANS Pressure Monitoring Systems consist of the sterile, single-use BIOTRANS Pressure Monitoring Kits and reusable BIOTRANS Reusable Sensor Bases and Monitor Adapter Cables.

The single-use BIOTRANS Pressure Monitoring Kits provide the sterile fluid pathway components that deliver IV solution to maintain catheter patency via the administration set components, transducer dome assembly and extension set, and convey the hemodynamic waveform from the patient's catheter to the reusable sensor (provided separately). The pressure waveform is conveyed to the sensor via two compliant diaphragms which are brought into intimate contact during set up of the device by the end-user.

All fluid contact occurs within the sterile single-use kit components.

6. **Intended Use:**

The BSI BIOTRANS Pressure Monitoring Kits are designed for use with the BIOTRANS Sensor Bases.

Kits containing integral 3- and 40 cc/hr flush devices are designed for use in physiologic pressure measurements where continuous flow is required to maintain catheter patency. The 40 cc/hr flush devices are included in Kits designed for neonatal applications in conjunction with a properly calibrated fluid delivery pump. Kits supplied without flush devices are intended for use in monitoring applications where no saline flush is required.

The predicate Medex Disposable Pressure Monitoring Kits are designed for use with the Medex Reusable Transducers.

The predicate Ohmeda and Utah Medical Products' Pressure Monitoring Kits which include 3cc flush devices are intended for use in physiologic pressure measurements which require continuous flow to maintain catheter patency. Those kits that employ a

30cc/hr flush device are intended for use in neonatal applications. This 30 cc flush device requires the use of a properly calibrated infusion pump.

Ohmeda's DTX Disposable Transducer Kit, Model TNF-R, does not include a flush device. No indications for use are indicated in its labeling for this model. The tacit assumption is that these kits are intended for pressure monitoring purposes where continuous flow is not required, or in conjunction with a stand-alone flush device.

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

The BIOTRANS Pressure Monitoring Kit domes incorporate a snap-fit configuration to ensure intimate mechanical contact of the dome diaphragm with the reusable sensor base diaphragm. The predicate Medex domes employ a bayonet mechanism for this purpose.

The BIOTRANS Kits are available in configurations that employ the silicone rubber component of the flush control device as a pressure relief mechanism. This mechanism is only available as an integral part of fast flush and flow control devices of the predicate devices.

Although the same generic materials and components are used for BIOTRANS and predicate devices, different formulations and vendors are used.

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

The BIOTRANS domes, when affixed to the BIOTRANS reusable sensor bases, meet *American National Standard for Blood Pressure Transducers (ANSI/AAMI BP22-1994)* performance and safety requirements. These requirements are also met by the predicate Medex reusable pressure transducers.

After exposure to pressures up to 4000 mm Hg, as required in ANSI/AAMI BP22-1994, BIOTRANS sensors meet accuracy and safety requirements, indicating that the pressure relief mechanism provides the sensor with adequate protection from overpressure.

All dome assembly materials meet the FDA and ISO biocompatibility requirements listed in ISO-10993-1 and G95-1, respectively. All other materials are either currently employed in legally marketed products with identical blood exposure, or are used in the fabrication of devices with a long history of safe and effective use for applications identical to those indicated for the BIOTRANS Pressure Monitoring Kits.

All bonded joints meet tensile and leak test requirements listed in International Standard ISO 8536-4 *Infusion equipment for medical use- Part 4: Infusion sets for single use.*

BSI's administration sets have been marketed in Asia and Europe for over 5 years with no history of complaints. They are of identical design to administration sets currently marketed in the US.

9. Conclusion:

The BIOTRANS Pressure Monitoring Kits meet performance and safety standards listed in *American National Standard for Blood Pressure Transducers* and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1998

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

Re: K981747
Biotrans™ Pressure Monitoring Kits
Regulatory Class: II (two)
Product Code: 74 DRS
Dated: August 11, 1998
Received: August 11, 1998

Dear Mr. Shulze:

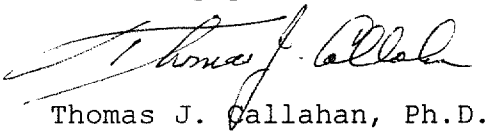
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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

Appendix 1

510(k) Number (if known): K981747

Device Name: BIOSENSORS INTERNATIONAL'S BIOTRANS™ PRESSURE MONITORING KITS

Indications For Use:

The BSI BIOTRANS Pressure Monitoring Kits are designed for use with BIOTRANS Sensor Bases.

Kits containing integral 3- and 40 cc/hr flush device are designed for use in physiologic pressure measurements where continuous flow is required to maintain catheter patency. The 40 cc/hr flush devices are included in Kits designed for neonatal applications in conjunction with a properly calibrated fluid delivery pump.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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