SEP 4 1998

K973477

BIOSENSORS EMBOLECTOMY CATHETER PREMARKET NOTIFICATION

510K SUMMARY
Prepared: August 11, 1997

1. **Submitted by:**

John Shulze
Sunscope International, Inc.
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2. **Contact Person:**

John Shulze

3. **Device Identification:**

Trade Name:	Biosensors Embolectomy Catheter
Common Name:	Embolectomy Catheter
Classification Name:	Catheter, Embolectomy

4. **Predicate Device(s):**

Baxter Healthcare's Fogarty® Arterial Embolectomy Catheter

5. **Device Description:**

Biosensors International (BI) has developed an embolectomy catheter that is equivalent in design and performance to embolectomy catheters currently marketed by Baxter. BSI's embolectomy catheters are configured as single lumen, balloon-tipped catheters. The catheters vary in length and diameter to accommodate various thrombotic obstruction and vessel lumen sizes. They are supplied in 3, 4, 5, 6, and 7 French diameters, with inflated balloon diameters of 6, 9, 11, 13, and 14 mm, respectively.

The catheters are color coded, and have black distance markings at 10 cm intervals (with "0" cm located at the distal catheter tip.)

The proximal end of the flexible catheters terminate in a rigid, winged adapter with female luer lock port to permit attachment to a stylet for stiffening the catheter during insertion, or sterile syringe during balloon inflation. The distal end of the catheters terminate in a latex-coated tip immediately distal to the latex balloons. The latex balloons lie flat against the catheters during insertion through the vasculature and lesion, and are inflated with sterile isotonic saline or other appropriate sterile solution during embolectomy procedures.

The catheters are supplied with a stainless steel stylet inserted in their lumens. The stylets terminate proximally in a rigid male luer adapter that mates with the female luer

of the catheters. The stylets can be used, when appropriate, to add rigidity to the catheters to aid in their insertion.

6. **Intended Use:**

The Biosensors Embolectomy Catheter is indicated for use in the removal of emboli and thrombi from the arterial system. The catheter should be used only by a physician with surgical skill in the vascular system.

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

The design of the Biosensors 3 through 7 Fr. embolectomy catheters is identical to that of the predicate devices. All of the catheter tips (3-7 Fr.) are latex-coated to minimize the potential for vessel trauma during catheter insertion. Both the Biosensors and Baxter 3 French embolectomy catheters terminate in a latex-coated spring tip.

Inflatable latex balloons are affixed at the distal tips of the Biosensors and Baxter catheters, which are inflated with an appropriate sterile liquid during embolectomy procedures. Placement of distance markings on the catheters are identical. The proximal ends of the flexible catheters terminate in rigid, winged adapters with female luer ports to provide for attachment to an inflation syringe.

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

Biosensors International has developed an embolectomy catheter that is substantially equivalent in function to the predicate Baxter embolectomy catheters. The materials used in the fabrication of Biosensors embolectomy catheters are identical to those used for other Biosensors catheters which also are exposed to circulating blood for a short period of time, and, therefore have identical biocompatibility requirements as the embolectomy catheters.

Further, test data collected on the burst and pull strength of the balloon, balloon inflation volume accuracy, tensile strength of the catheter, and leak test data demonstrate that Biosensors International Embolectomy Catheters' performance is substantially equivalent to that of the predicate devices, and no new questions concerning safety and efficacy are raised.

9. **Conclusion:**

Based on the test data gathered, Biosensors International Embolectomy Catheters are substantially equivalent to Baxter Healthcare's embolectomy catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

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

Re: K973477
Trade Name: Biosensors Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: June 8, 1998
Received: June 9, 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) 594-4586. 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

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): K973477

Device Name: BIOSENSORS EMBOLECTOMY CATHETER

Indications For Use:

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Judith Danielson for Doyle Gantt
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973477

Prescription Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)