NOV - 4 2005 K051274

Appendix A10 — 510(k) Summary

Date Prepared: 10/6/2005

Submitter/Contact:
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Trade Name: Somanetics INVOS® 5100B and SSFB Somatic SomaSensor®

Accessories:

SAFB	Adult Cerebral SomaSensor (>40 kg)
SAFB-SM	Small Adult Cerebral SomaSensor (>40 kg)
SPFB	Pediatric Cerebral SomaSensor (<40 kg)
SSFB	Somatic SomaSensor
BRCB	Bilateral Reusable Sensor Cable
5100B-W	One-year Extension of Warranty
313137A	5100B System Operations Manual
5100B-FTD	Field Test Device
5100B-STD	Portable Mobile Stand
5100B-TC	Travel Case
DB9DB9	Computer Connection Serial Cable
5100B-DD	3.5" Floppy Disk Drive

Classification Name: Tissue Oximeter

Common Name: Oximeter/Cerebral Oximeter/NIRS

Regulatory Class: Oximeters have been classified in Class II by the Cardiovascular device panel, see 21 CFR 870.2700, product code MUD.

Performance Stds: FDA has not developed performance standards for this device. Also, oximeters have not been assigned any special controls.

Indications for Use: The noninvasive INVOS 5100B is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain of an individual. It also is intended for use as an adjunct trend monitor of hemoglobin oxygen saturation of blood in a region of skeletal muscle tissue beneath the sensor in infants, children, or adults at risk for reduced-flow or no-flow ischemic states. The prospective clinical value of data from the INVOS System has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.

Device Description:

The principles of operation of the cerebral oximeter system are based on the assumption that hemoglobin exists in two principal forms in the blood: oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb). Functional oxygen saturation (SO_2) is defined as the ratio of oxyhemoglobin (HbO_2) to total hemoglobin (HbO_2 + Hb) and is commonly presented as a percentage.

$$SO_2 = \frac{HbO_2}{HbO_2 + Hb} \times 100\%$$

Since oxygenated and reduced hemoglobin are different colors and absorb light as a known function of wavelength, selected wavelengths of light can be used to assess the relative percentage of these two constituents. This fundamental approach of assessing the color of blood using various wavelengths of light to measure hemoglobin oxygen saturation trends is used in all currently marketed oximetry systems.

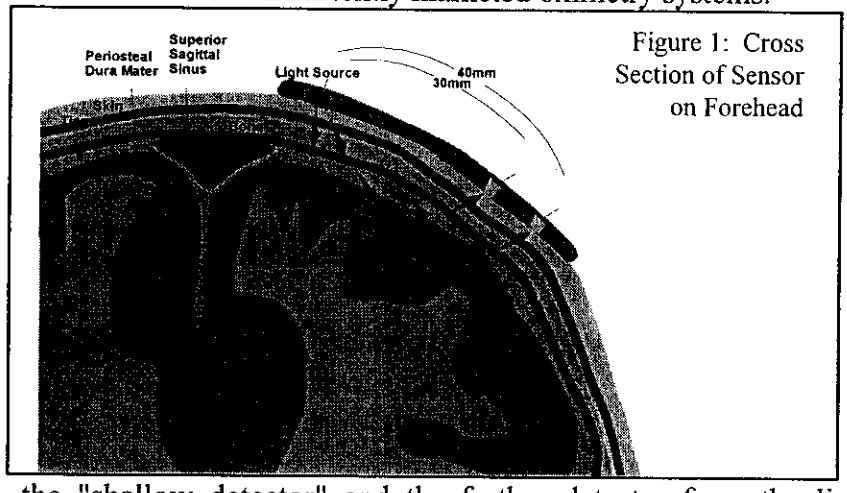

Figure 1: Cross Section of Sensor on Forehead

For cerebral monitoring, a disposable sensor of medical grade materials is applied to the patient's forehead (Figure 1). The sensor incorporates a light source and two return signal detectors at different pre-determined distances from the light source. The signal detector nearest the light source (3 cm) is considered the "shallow detector" and the further detector from the light source (4 cm) the "deep detector."

While the light reaching the deep detector has sampled about the same amount of skin, scalp, and skull as the light reaching the shallow detector, it has sampled more brain tissue. This difference is used to help separate out the brain signal and suppress anatomical differences in patients. The additional information unique to the deep signal return is predominately from brain tissue blood which is composed mostly of venous blood. The information contained in the shallow and deep signal returns is processed by an algorithm to measure changes in hemoglobin oxygen saturation in a small region of tissue beneath the sensor, predominately in the brain.

For non-cerebral monitoring, a somatic sensor which is similar to the cerebral sensor is placed on skeletal muscle in an area free of large fat deposits, bony protuberances and hair. Since the tissue being interrogated is relatively homogeneous, the resultant rSO_2 index is an average of the hemoglobin oxygen saturation of blood in the region of tissue below the sensor.

The SomaSensor is connected to a preamplifier (1.4 x 7.65 x 3.75 in.) which is placed close to the patient and amplifies the rSO_2 signal. The signal is then carried to a display unit (8.4 x 9.6 x 8.5 in.) where the values and trends are displayed on the screen. The display unit controls all functions of the system with selections made by keys with on-screen labels. The system will operate for up to 120 minutes on battery, enabling patient transport without loss of data.

Substantial Equivalence:

The INVOS 5100B is substantially equivalent to the INVOS 5100 (K001842) in that the method of measurement, electronics, packaging and physical configuration are identical but the indications for use are expanded. The newer INVOS 5100B will operate with the SSFB Somatic SomaSensor to monitor skeletal muscle tissue. The indications for use are substantially equivalent to the indications for the Spectros Corporation T-Stat™ 303 Microvascular Tissue Oximeter (K040684) and the Hutchinson InSpectra (K963903).

Nonclinical Testing:

The INVOS 5100B is identical to the INVOS 5100 Adult/Pediatric Cerebral Oximeter System (K001842) and the SSFB Somatic SomaSensor is identical to the SAFB (K001842) except that it is supplied with a larger adhesive pad and revised labeling. The result of previous validations, including software validations for a moderate level of concern, confirms that the model 5100B performs according to published specifications.

Clinical Testing:

- An adult volunteer hypoxia study (K971628) demonstrated that the INVOS System was able to accurately track changes in cerebral blood oxygen saturation as compared with co-oximetry analysis of blood samples over a wide range of arterial saturation repeated at two levels of arterial carbon dioxide.
- A study in the pediatric cath lab (K001842) demonstrated that the INVOS System also accurately tracked changes in cerebral oxygen saturation as compared with co-oximetry analysis of blood samples in children with congenital heart defects during sedation and during supplemental oxygen administration.
- An animal study using isolated perfused porcine limbs demonstrated that the INVOS System was able to track changes in blood oxygen saturation in skeletal muscle tissue over a range of 5% to 95% with a bias of 1 and standard deviation of 7.
- Multiple peer-reviewed studies have shown the INVOS System provides skeletal muscle somatic oxygen saturation readings in low and no flow ischemic states in human and animal trials.
- Two published studies demonstrate the ability of the INVOS System somatic saturation to reflect the intensity of exercise.
- Somatic saturation has been shown to correlate with mixed venous oxygen saturation and has the potential to predict the onset of anaerobic metabolism.

Conclusion:

The INVOS 5100B and SSFB Somatic SomaSensor were found to be substantially equivalent to the previously marketed INVOS 5100 and SAFB SomaSensor (K001842) and the indications for use are substantially equivalent to the Spectros Corporation T-Stat 303 (K040684). No new questions of safety or effectiveness were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

Mr. Ronald A. Widman
Vice President, Medical Affairs
Somanetics Corporation
1653 East Maple Road
Troy, Michigan 48083-4208

Re: K051274
Trade/Device Name: INVOS 5100B Oximeter System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: October 6, 2005
Received: October 7, 2005

Dear Mr. Widman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K051274

Device Name: Somanetics INVOS® 5100B System and SSFB Somatic SomaSensor®

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(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K051274

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)