Section 8 — 510(k) Summary

1. **Date Prepared:** April 30, 1997 OCT 10 1997

2. **Submitter/Contact Person:**
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3. **Trade Name:** Somanetics INVOS® 3100A Cerebral Oximeter (INVOS) with SS-A SomaSensor®
Accessories:
SS-A Single-patient use sensor (SomaSensor)
3100-DD Disk Drive
3100-TC Travel Case
3100A-M Additional User Manual
311963 Null Modem Cable

4. **Classification Name:** Oximeters

5. **Common Name:** Cerebral Oximeter

6. **Predicate Device:** Somanetics INVOS® 3100A Cerebral Oximeter with 3100-SD SomaSensor® (K960614)

7. **Indications for Use:** The noninvasive INVOS 3100A Cerebral Oximeter should be used in adults as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood in the brain of an individual. Because INVOS values are relative within an individual, the INVOS should not be used as the sole basis for decisions as to diagnosis or therapy. The value of data from the INVOS has not been demonstrated in disease states.

Contraindications: None.

8. **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.

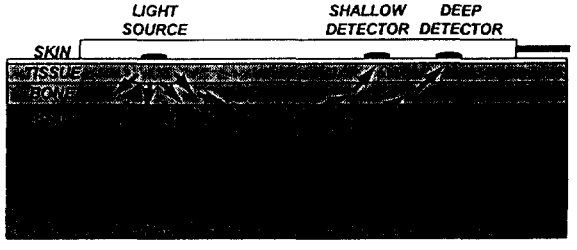

Figure 1: Cross Section of Sensor on Forehead

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.

The SomaSensor is connected to a preamplifier (1.75 x 7.4 x 5.4 in.) which is placed close to the patient and amplifies the rSO_2 signal. The signal is then carried to a display unit (6.5 x 12.5 x 13.5 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 20 minutes on battery, enabling patient transport without loss of data.

9. Substantial Equivalence:

The INVOS SS-A SomaSensor is substantially equivalent to the INVOS 3100-SD SomaSensor in that the method of measurement, physical configuration and indications for use are identical. The newer SS-A has an LED light source like the 3100-SD, however, the SS-A source is approximately ten times brighter. As a result of both bench testing and a clinical study, the SS-A SomaSensor was shown to be substantially equivalent to the 3100-SD.

10. Nonclinical Testing:

The SS-A SomaSensor and INVOS system has been tested in the following areas to ensure substantial equivalence with the predicate device:

INVOS system repeatability, high potential and current leakage, sensor temperature rise, sensor light output, system component interchangeability and safety/performance.

The INVOS system has been granted the GS and CE marks as certification of compliance with EN 60601-1/08.90 and EC Directive 93/42/EEC Annex III, Medical Devices. The INVOS system has been granted the ETL mark as certification of compliance with UL 2601.1 and CSA C22.2 No. 601.1 safety standards.

11. Clinical Testing:

A volunteer hypoxia study was performed with the SS-A SomaSensor in support of this premarket notification as described below.

The volunteer hypoxia study objective was to compare the INVOS rSO_2 index with blood oxygen saturation measurements performed off-line on a co-oximeter during moderate hypoxia and hypercapnia. The study consisted of 20 volunteers with demographics as follows: 19 light and 1 dark skinned subjects; 12 males and 8 females. Age ranged from 20 to 36 years, with a median of 26.5 years. Five sets of data were collected comparing rSO_2 to a combination of arterial and jugular venous blood oxygen saturations over an arterial saturation range of 74-100% with $etCO_2$ controlled to each individual's resting level. The same five steps were then repeated at an elevated level of $etCO_2$ to raise cerebral blood flow (CBF) by increasing inspired CO_2 by 4 to 7 mmHg such that CBF increased about 12-21% above normal.

Arterial catheters were placed in the left arm in 18 subjects and in the right arm in two. Jugular venous catheters were placed in the right internal jugular vein (IJ) without incident in all subjects. One data point was rejected due to sampling errors (jugular venous sample was delayed into the next step due to catheter problems). Values of rSO_2 were compared to an estimate of the saturation of all the blood in the region of brain beneath the sensor, calculated as:

$$fSO_2 = (0.25 * SaO_2) + (0.75 * SjvO_2)$$

where SaO_2 and $SjvO_2$ are arterial and jugular bulb venous blood sample oxygen saturations as analyzed on a co-oximeter.

Trend agreement between fSO_2 (as calculated from arterial and jugular venous blood samples) and rSO_2 index at both levels of CBF was very high in the 20 individuals, mean individual r^2=0.95 (range 0.82 to 0.99). The ability of the INVOS to accurately measure trends in saturation was within ±3%, combined bias and standard deviation, including co-oximeter and blood sampling errors. The trend measurement correlation coefficient was r^2=0.96 and trend bias and standard deviation were 0.3 ± 2.9%. The overall mean bias between fSO_2 and rSO_2 index for 19 individuals (one subject's absolute data was rejected due to low Signal Quality Index) was 2.49. The mean standard deviation of the rSO_2 index for all 42 individuals was 2.1%.

12. Conclusions Drawn from the Nonclinical Testing and Clinical Study:

The nonclinical testing of the INVOS 3100A with the modified SS-A SomaSensor support the conclusion that the modified system is safe and effective for patient use and substantially equivalent to the predicate device. Additionally, the testing supports the contention that the INVOS is able to perform with similar levels of accuracy and performance as the predicate device.

In the hypoxia study during levels of moderate hypoxia during normo- and hypercapnia, the transition accuracy of the INVOS as compared to the fSO_2 estimate from blood samples was within ±3% (combined bias and standard deviation), correlation coefficient $r^2 = 0.96$ (predicate device transition accuracy is ±4.8%, $r^2 = 0.87$). Rejection of non-brain signal was evaluated during changes in $etCO_2$ (which produced changes in cerebral blood flow) at constant SaO_2 (to hold oxygen saturation in the scalp constant). Transition error was calculated during increased $etCO_2$ of 4-7 mmHg during constant SaO_2 (increased cerebral blood flow) and compared to transition error during changes in SaO_2 of up to 25% during constant CO_2 (systemic hypoxia). Both were within 4%, supporting a predominant brain measurement (predicate device was within 5.4%).

No complications or side effects directly attributable to the Oximeter were reported during the study. No adverse reactions to the sensor adhesive were reported. The SQI (Signal Quality Index), which evaluates whether conditions are optimum for accurate absolute measurements, indicated the data from one subject was not suitable for absolute comparisons of rSO_2 and fSO_2. In this subject, however, the trend data was good and was included in the trend accuracy statistics.

Since there were improvements in virtually all of the accuracy and safety areas, the combined non-clinical and clinical testing support the conclusion that the INVOS is safe, can accurately measure trends in regional hemoglobin oxygen saturation of blood in the brain of an individual and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Ronald A. Widman
Director of Medical Affairs
Somanetics Corporation
1653 East Maple Road
Troy, Michigan 48083

OCT 10 1997

Re: K971628
Trade Name: Somanetics INVOS® 3100A Cerebral Oximeter for use with modified SS-A SomaSensor
Regulatory Class: II
Product Code: 74DQA
Dated: April 30, 1997
Received: May 2, 1997

Dear Mr. Widman:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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/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): K971628

Device Name: Somanetics INVOS® 3100A Cerebral Oximeter and SS-A SomaSensor

Indications For Use:

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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)

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

(Optional Format 1-2-96)