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Section 8 510(k) Summary

1. **Date Prepared:** May 31, 1996

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3. **Trade Name:** Somanetics INVOS® 3100A Cerebral Oximeter (INVOS)
Accessories:
3100-SD Single-patient use sensor (SomaSensor)
3100-DD Disk Drive
3100-TC Travel Case
3100A-M Additional User Manual

4. **Classification Name:** Oximeters

5. **Common Name:** Cerebral Oximeter

6. **Predicate Devices:** Nellcor N-200 Pulse Oximeter (K863784)
Baxter SAT-II Intravascular Oximetry System (K884329)

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.

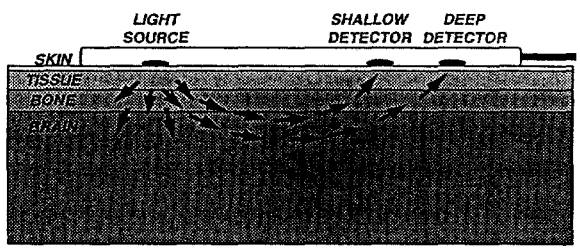

Figure 1: Cross Section of Sensor on Forehead

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 is substantially equivalent to the common pulse oximeter and to intravascular oximetry systems. It has the same intended use as generic oximeters (e.g. pulse oximeters, ear oximeters, and intravascular catheter oximeters), namely to measure blood oxygen saturation. All such devices utilize spectrophotometric techniques to assess the color of blood in order to determine the hemoglobin oxygen saturation.

The INVOS is similar to the common pulse oximeter in its patient interface and method of operation. Both devices are applied to the surface of the skin, pass light through highly vascularized tissue, capture returned light, and analyze it to provide an estimate of functional hemoglobin oxygen saturation in the in vivo blood by analyzing the color of that blood. Both employ a two-wavelength near-infrared spectrophotometric technique using LED light sources and photodiode detectors. Pulse oximeters make their measurements on a finger, toe, or earlobe. The INVOS makes its measurement on the forehead.

Whereas pulse oximeters emphasize arterial hemoglobin oxygen saturation and the INVOS measures predominately venous hemoglobin oxygen saturation, the clinical interpretation of the INVOS measurement is similar to that of currently marketed intravascular catheter oximeter systems that measure mixed venous oxygen saturation. Specifically, intravascular catheter oximeter systems continuously measure trends in blood oxygen saturation in the pulmonary artery which is comprised of mixed venous blood. The INVOS measures trends in oxygen saturation in the region of the brain beneath the sensor which contains blood that is a majority venous blood. As with intravascular catheter oximeter systems, changes in INVOS values reflect changes in the balance between oxygen delivery and oxygen consumption and alert the clinician of the potential for a problem that is worthy of investigation.

Unlike pulse oximeters, the INVOS does not depend on a pulse signal to function. During periods when pulse signals are low or non-existent (e.g. cardiopulmonary bypass, hypothermia, hypotension, cardiac arrhythmias, etc.) the INVOS is able to continue to function, providing potentially important noninvasive information regarding oxygenation.

Unlike intravascular catheter oximetry systems, the INVOS is noninvasive and the INVOS makes venous oxygen saturation information available with less risk, enabling its use on patients for whom the use of a pulmonary artery catheter is not warranted.

10. Nonclinical Testing:

The INVOS has been tested in the following areas to ensure substantial equivalence with the predicate devices:

INVOS linearity, accuracy, noise levels, operating and storage temperatures, input voltage, altitude, patient safety, user safety, EMI/RFI interference and susceptibility, battery discharge time, power consumption, component stress, component heating, fan cooling capacity, shipping carton validation and compliance with voluntary standards CSA C22.2 No. 601.1, UL 2601.1, EC Directive 93/42/EEC Annex III, Medical Devices and EN 60601-1/08.90.

The SomaSensor has been tested in the following areas to ensure substantial equivalence with the predicate devices:

Linearity, repeatability, operating and storage temperatures, potential overheating, light output, patient and user safety, biocompatability, EMI/RFI interference and

susceptibility and compliance with voluntary standards CSA C22.2 No. 601.1, UL 2601.1, EC Directive 93/42/EEC Annex III, Medical Devices and EN 60601-1/08.90.

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:

Two clinical studies were performed in support of the premarket notification as described below.

The first was a volunteer hypoxia study whose 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 30 volunteers with demographics as follows: 21 light, 5 medium and 4 dark skinned subjects; 19 males and 11 females. Age ranged from 19 to 40 years, with a median of 25 years. Six 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 73-100%. The six steps were then repeated at an elevated level of cerebral blood flow (CBF) obtained by increasing inspired CO_2 such that CBF increased about 12-30%.

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 individuals, mean individual r^2=0.947 (range 0.805 to 0.991). The ability of the INVOS to accurately measure trends in saturation was within ±4.9% (combined bias and standard deviation). The trend measurement correlation coefficient was r=0.935 and bias and standard deviation were 0.219 ± 4.61. The overall mean bias between fSO_2 and rSO_2 index was 1.33. Standard deviations of the absolute difference between fSO_2 and rSO_2 index for individuals averaged 3.08. Skin condition was observed before and after placement of the SomaSensor. No instances of irritation were observed.

The second study evaluated 27 patients during carotid endarterectomy (CEA) with demographics as follows: 21 males and 6 females, all Caucasian. Its purpose was to evaluate the ability of the INVOS system to detect and differentiate mild to severe ischemia caused by clamping of the common carotid artery. Twenty-two of this group had surgery performed under general anesthesia and five under regional anesthesia. One patient was operated twice for both left and right CEAs. Changes in rSO_2 index were compared to changes in mean middle cerebral artery flow velocity (MCAVm) as measured by transcranial Doppler (TCD) and EEG changes as evaluated by a trained observer using 10-channel analog recordings.

Correlation between changes in rSO_2 index and changes in MCAVm during cross-clamp of the common carotid artery was r=0.806. The INVOS detected changes in oxygenation

which preceded EEG changes during cross-clamp of the carotid artery, $p<0.03$. Comparison of the changes in MCAVm and rSO_2 index were made during cross-clamp of only the external carotid artery in six of the 27 subjects. The percentage change in both rSO_2 index and MCAVm when clamping the external carotid was generally lower than when clamping the common carotid, although, due to the small sample, statistical significance could not be reached.

Skin condition was observed in the twenty-seven study subjects (one twice) and one (008) who had a sensor placed but on whom TCD monitoring could not be accomplished. Condition was evaluated immediately after removal of the sensor in all twenty-eight and included a 24-hour follow-up in eleven. No instances of adverse reactions or skin irritation were observed.

Using continuous data recorded during the CEA study on disk, the amount of time was calculated when, due to noise, electrical interference, excessive ambient light or other events, the INVOS was not able to calculate a value for rSO_2 index. Combining all patients enrolled in the study and 1 additional subject (008) who was not enrolled in the study due to lack of TCD monitoring, the INVOS was operational 99.66% of the time in the O.R. or less than 10 minutes of data were lost in over 48 hours of monitoring.

12. Conclusions Drawn from the Nonclinical and Clinical Studies:

The nonclinical testing of the INVOS and the SomaSensor support the conclusion that the INVOS system is safe for patient use, similar to the predicate devices. Additionally, the testing supports the contention that the INVOS is able to perform with similar levels of accuracy and performance as the predicates.

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 ±5% (combined bias and standard deviation), correlation coefficient $r = 0.935$. Cerebral trending accuracy was measured by calculating transition error during changes in CO_2 of 4-10 mmHg during constant SaO_2 (changes in cerebral blood flow) and transition error during changes in SaO_2 of up to 27% during constant CO_2 (systemic hypoxia). Both were within 5.5%, supporting a predominant brain measurement.

In the carotid endarterectomy study, changes in rSO_2 index correlated well with MCAVm changes and its performance supported its substantial equivalence with other measures of cerebral function monitoring. The ability of the INVOS to document periods of cerebral ischemia as confirmed by EEG changes was as good as TCD measurement of changes in MCAVm ($p<0.01$). Changes in rSO_2 index during extracranial ischemia (caused by clamping just the external carotid artery) were small compared to intracranial ischemia. When sufficient collateral flow was present in the brain, changes in rSO_2 index during clamping were minimal despite presumed extracranial desaturation (since established collaterals do not exist extracranially), providing evidence for an INVOS measurement predominately from the brain.

No complications or side effects directly attributable to the Oximeter were reported during either study. No adverse reactions to the sensor adhesive were reported.

The INVOS system provided reliable monitoring 99.66% of the time in 28 cases during use in the operating room.

The combined nonclinical and clinical testing support the conclusion that the INVOS can measure trends in regional hemoglobin oxygen saturation of blood in the brain of an individual and is substantially equivalent to the predicate devices.