MAY - 4 2010

K 100523

510(k) Summary

In accordance with 21 CFR Part 807.92, this summary is submitted by:

Hygia Health Services, Inc.
434 Industrial Lane
Birmingham, Alabama 35211
Phone: (205) 314-3920
Fax: (205) 314-3959

Date Prepared: February 23, 2010

1. Contact Person

Mr. Lake Trechsel
R&D Engineer
Phone: (205) 314-3920
Fax: (205) 314-3959
Email: lake.trechsel@hygia.net

2. Name of Device

Classification Name:	Oximeter, Tissue Saturation
Common Name:	Oximeter, Cerebral/Somatic
Trade or Proprietary Name:	Hygia Health Services Reprocessed Cerebral-Somatic Oximetry Sensors

3. Predicate Device

Corresponding Somanetics oximetry sensors legally marketed under various 510(k) premarket notifications:

Somanetics Corp.	K082327
Somanetics Corp.	K080769
Somanetics Corp.	K051274
Somanetics Corp.	K001842
Somanetics Corp.	K971628
Somanetics Corp.	K960614

4. Device Description

The Hygia Health Services Reprocessed Cerebral-Somatic Oximetry Sensors (CSS) are optical devices which use dual-wavelength light to determine a patient's current regional oxygen saturation level. Once a sensor has been applied to the patient, a light source in the sensor sends red and near-infrared light through the skin surface and photodiodes measure the reflected light. This signal is sent back to a monitor which calculates the patient's trending oxygenation levels.

5. Device Intended Use

The Hygia Health Services Reprocessed CSS are intended to be used in the same manner as the predicate devices. They are designed to be applied to the forehead and other appropriate portions of the body to measure regional oxygenation saturation during surgery or other applications related to the use of anesthesia. The devices are intended to be used in hospitals.

6. Indications For Use

The Hygia Health Services Reprocessed Pediatric and Adult Cerebral-Somatic Oximetry Sensors are indicated for use when continuous noninvasive oxygen saturation is required for pediatric patients weighing < 40 kg and adult patients weighing > 40 kg, respectively. The Hygia reprocessed sensor has been validated with the OEM's Cerebral/Somatic Oximeter, Model 5100C and is intended to be used with the Cerebral/Somatic Oximeter, Model 5100C only.

The noninvasive 5100C Cerebral/Somatic Oximeter is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states. The prospective clinical value of data from the 5100C Cerebral/Somatic Oximeter has not been demonstrated in disease states. The OEM suggests the 5100C Cerebral/Somatic Oximeter should not be used as the sole basis for diagnosis or therapy.

7. Technological Characteristics

The Hygia Health Services CSS are identical to the original OEM devices in reference to the technological characteristics.

8. Performance Data

Functional testing, cleaning validation, and biocompatibility data demonstrates that the reprocessed oximetry sensors perform as intended, and are safe and effective.

9. Conclusion

Based on the assessment of functional testing, cleaning validation, and biocompatibility data, Hygia Health Services concludes that the Hygia Health Services Reprocessed CSS are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY – 4 2010

Hygia Health Services, Inc.
% Mr. Lake Trechsel
R & D Engineer
434 Industrial Lane
Birmingham, Alabama 35211

Re: K100523
Trade/Device Name: Hygia Health Services Reprocessed Cerebral-Somatic Oximetry Sensor (CSS)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NMD
Dated: February 23, 2010
Received: February 25, 2010

Dear Mr. Trechsel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K 100523

Device Name: Hygia Health Services Reprocessed Cerebral-Somatic Oximetry Sensor (CSS)

Indications For Use:

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Prescription Use __Yes___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __No___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Updegrove for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100523

PRODUCT SUBMISSION CHART

OEM Catalog #	Hygia Catalog #	Product Description	Intended Oximeter	Maximum # of Reprocessing Cycles
SAFB-SM	HHS-SAFB-SM	Adult Cerebral-Somatic Oximetry Sensor	Somanetics INVOS 5100C	2
SPFB-USA	HHS-SPFB-USA	Pediatric Cerebral-Somatic Oximetry Sensor	Somanetics INVOS 5100C	2

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100523