Section 5 – Summary of Safety & Effectiveness

DEC - 3 2010

510(k) Summary

Submitter [807.92(a)(1)]:

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Date prepared [807.92(a)(1)]: **April 13, 2010**

Trade, Common and Classification Name [807.92(a)(2)]:

Trade / Proprietary Name	Common / Usual Name	Classification Name	Product Code	Class	Regulation Number
SenTec Digital Monitoring System (SDMS) SenTec Digital Monitor (SDM), sensors, accessories for sensor application/maintenance; V-STATS™ PC-based trend reporting, data analysis and remote monitoring Software for the SDM	Cutaneous Carbon Dioxide Monitor	Monitor, Carbon-Dioxide, Cutaneous	73 LKD	II	21 CFR Part 868.2480
	Pulse Oximeter	Oximeter	74 DQA	II	21 CFR Part 870.2700
	Pulse Oximeter	Oximeter, Ear	74 DPZ	II	21 CFR Part 870.2710

Substantially Equivalent to [807.92(a)(3)]:

	Device	Manufacturer	Comment
K071672	SenTec Digital Monitoring System	SenTec AG	This device is predicate for PCO2, SpO2, and PR monitoring using the ear lobe as monitoring site in adult and pediatric patients, for PCO2 only monitoring in adult, pediatric and neonatal patients using conventional PCO2 measurement sites as well as for the new V-Sign™ Sensor 2.
K043003	**TCM4**/40 Monitoring System	Radiometer Medical ApS	The TOSCA 500 is predicate for PCO2, SpO2, and PR monitoring using the forehead and cheek as a monitoring site in adult and pediatric patients as well as for the new parameter 'Pulsation Index'.
K063434	TOSCA 500 tcPCO2, SpO2 and PR Monitoring system	Radiometer Basel AG	These two devices are predicates for the expanded sensor temperature and site time management as well as for the new parameter 'Heating Power' being introduced by the modified SDM firmware.
K060675	Reusable EnviteC SoftTipY SpO2 Sensors	EnviteC-Wismar GmbH	These two devices are predicate for conventional SpO2 and PR monitoring on a patient's digit using SenTec's new SpO2 Soft Sensor being connected to the SDM with SenTec's new SpO2 Adapter Cable.
K991823	N-395 Pulse Oximeter	Nellcor Puritan Bennett, Inc.	

	Device	Manufacturer	Comment
K961450	Score Software (PC Software)	Nellcor Puritan Bennett, Inc.	These two devices are predicate for V-STATS™ (SenTec's optional PC software). Score Software is predicate for V-STATS™'s claim to download data from the internal memory of the SDM for subsequent display, analysis and reporting. Oxinet III software is predicate for V-STATS™'s claim for remote monitoring. [Note: Nellcor's OxiNet III is a private label of the Bernoulli Software for pulse oximeters]
K091461	Bernoulli™ Management System, **Oxinet III** and Lifegard Vue	Cardiopulmonary Corporation	

Reason For Submission: Additional or Expanded Indications

Description of the device [807.92(a)(4)]:

The SenTec Digital Monitoring System (SDMS) as listed under K071672 is a device consisting of a stand-alone monitor [SenTec Digital Monitor (SDM)], a digital sensor [V-Sign™ Sensor (model VS-A/P)], connecting cables, and accessories for sensor application and maintenance. The SDMS is designed for the continuous and non-invasive monitoring of carbon dioxide partial pressure (PCO2), functional oxygen saturation (SpO2), and pulse rate (PR) using the ear lobe as monitoring site in adult and pediatric patients. It is furthermore designed for PCO2-only monitoring in adult, pediatric and neonatal patients using conventional PCO2 measurement sites.

This new 510(k) introduces the following additional features/functions to the SDMS:

- V-Sign™ Sensor 2 (model VS-A/P/N) *[successor of V-Sign™ Sensor (model VS-A/P) with improved embedded hardware/software]* for PCO2, SpO2, PR monitoring using the ear lobe, the forehead or the check as monitoring site in adult and pediatric patients as well as for PCO2-only monitoring in adult, pediatric and neonatal patients using conventional PCO2 measurement sites
- SpO2 Soft Sensor (models RSS-L, RSS-M, RSS-S) with the SpO2 Adapter Cable (model SC-XX; where XX=150, 250, or 750) for continuous and non-invasive SpO2/PR monitoring in patients weighing more than 20 kg. These conventional oximetry sensors, which are applied to a patient's digit, must be connected to the SDM by using the new SpO2 Adapter Cable.
- V-STATS™, an optional PC software application for remote monitoring and/or trend reporting and statistical analysis of the data measured with the SDMS.

This new 510(k) furthermore introduces the following modifications/enhancements:

- Modified intended use for the Multi-Site Attachment Rings: In K071672 the Multi-Site Attachment Rings (model MAR-MI, formerly designated MAR-A/P; and model MAR-SF, formerly designated MAR-A/P/N) were listed for continuous and non-invasive PCO2-only monitoring. This new 510(k) submission expands the intended use for both models to additionally include continuous and noninvasive SpO2 and PR monitoring if V-Sign™ Sensor 2 (model VS-A/P/N) is applied to the forehead or cheek of adult or pediatric patients. In K071672 the Multi-Site Attachment Ring (model MAR-MI) was listed for use in adult and pediatric patients. This new 510(k) submission expands the intended use for the Multi-Site Attachment Ring (model MAR-MI) to additionally include the neonatal population. Proposed labeling states that model MAR-MI can be used for patients with mature and intact skin, whereas for patients with sensitive/fragile skin model MAR-SF must be used.
- Modified firmware for the SenTec Digital Monitor: the modified firmware of the SDM introduces an expanded sensor temperature / site time management two new monitoring parameters (Pulsation Index and Heating Power). It furthermore supports the new sensors being introduced with this new 510(k).

Intended Use [807.92(a)(5)]:

The SenTec Digital Monitoring System – consisting of the *SenTec Digital Monitor (SDM), Sensors* and *Accessories* - is indicated for continuous, non-invasive patient monitoring. The SenTec Digital Monitoring System is indicated for use in hospitals, hospital-type facilities, intra-hospital transport environments, and – if under clinical supervision – home environments. The SenTec Digital Monitoring System is for prescription use only.

V-Sign™ Sensor, model VS-A/P, and *V-Sign™ Sensor 2*, model VS-A/P/N, are indicated for use with the SenTec Digital Monitor when continuous non-invasive monitoring of carbon dioxide tension, oxygen saturation, and pulse rate are required for adult and pediatric patients. In neonatal patients the use of *V-Sign™ Sensor* and of *V-Sign™ Sensor 2* is indicated for carbon dioxide tension monitoring only.

SenTec's *Ear Clip*, model EC-MI, is intended for use with *V-Sign™ Sensor* or *V-Sign™ Sensor 2* when continuous, non-invasive carbon dioxide tension, oxygen saturation and pulse rate monitoring are required. The *Ear Clip* is for single-patient use and is indicated to attach *V-Sign™ Sensor* or *V-Sign™ Sensor 2* to the ear lobe of the patient. The use of the *Ear Clip* is contraindicated for patients whose ear-lobes are too small to ensure adequate sensor application.

SenTec's *Multi-Site Attachment Rings*, model MAR-SF and model MAR-MI, are intended to attach *V-Sign™ Sensor* or *V-Sign™ Sensor 2* to conventional measurement sites for carbon dioxide tension monitoring when continuous, non-invasive carbon dioxide tension monitoring is required for adult, pediatric, and neonatal patients. They are intended to attach the *V-Sign™ Sensor 2* to the forehead or the cheek when continuous, non-invasive carbon dioxide tension, oxygen saturation, and pulse rate monitoring is required for adult and pediatric patients. The *Multi-Site Attachment Rings*, model MAR-SF and model MAR-MI, are for single use.

SenTec's multi-compatible and reusable *SpO2 Soft Sensors*, models RSS-L, RSS-M and RSS-S, are indicated for use with the monitoring devices indicated in the respective sensor directions for use when continuous non-invasive monitoring of oxygen saturation, and pulse rate are required for patients weighing more than 20 kg.

V-STATS™ is an optional PC-based software which is indicated for use with the *SenTec Digital Monitor (SDM)* when remote monitoring and/or trend reporting and statistical analysis of the data measured by the SDM is required. *V-STATS™* is not intended to provide diagnosis, it is intended to supplement and not to replace any part of the SDM monitoring procedures.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Technological Characteristics [807.92(a)(6)]:

The SenTec Digital Monitoring System has the same indications for use as well as the same indicated patient population as the specified combination of the predicate devices.

Compared to the SDMS configuration cleared under K071672 the V-Sign™ Sensor (model VS-A/P), existing accessories (Digital Sensor Adapter Cable, Ear Clip, Multi-Site Attachment Rings, V-Sign™ Membrane Changer, Service Gas, Contact Gel) as well as the hardware and the majority of software features of the SenTec Digital Monitor (SDM) remain unchanged and therefore are identical to the SDMS configuration listed under K071672.

SenTec's new V-Sign™ Sensor 2 (model VS-A/P/N) is the successor of V-Sign™ Sensor (model VS-A/P) cleared under K071672. It uses the exact same basic principles of operation and the same technology as the predicate device. The differences are that it makes use of improved embedded hardware/software. These differences do not raise additional issues regarding safety and effectiveness.

SenTec's new RSS series 'SpO2 Soft Sensor' with the SC series SpO2 Adapter Cable is a reusable, conventional oximetry sensor which is applied to a patient's digit. It utilizes an existing EnviteC sensor design cleared under K060675.

All relevant patient monitoring features of the SenTec Digital Monitoring System are equivalent to the SDMS configuration listed under K071672, the TOSCA 500, the TCM 4 (as used with Electrode E5260 [PCO2-only]), and the Reusable EnviteC SoftTipY SpO2 Sensors (being used with Nellcor's N-395 pulse oximeter). The key features are:

A. Monitoring with heated PCO2/SpO2 or PCO2 Sensor
- same principles of operation (reflective 2 wavelength SpO2 measurement, and Severinghaus-type PCO2 electrode technology)
- sensors heated to an operator selectable SET temperature which is selectable by the operator
- equivalent or similar means to control sensor temperature and application time at the site (Site Timer)
- equivalent or similar sensor application means (adhesive Ear Clip and/or adhesive attachment rings)
- equivalent or similar sensor calibration unit integrated in monitor
- equivalent or similar accessories for sensor maintenance: membrane changer, contact gel, service gas

B. Monitoring with unheated, conventional SpO2 Sensor
- same principles of operation (transmissive 2 wavelength SpO2 measurement)
- equivalent recommendations for application time (Site Timer controlled in case of the SDMS)
- equivalent sensor application (sheath-like rubber tube being pushed onto finger tip)

C. General Monitoring features
- equivalent or similar methods to calculate/display the monitored parameters
- equivalent or similar alarms, messages and menu structure as predicate devices
- equivalent or similar interfacing and data management possibilities
- equivalent or similar configuration/management of parameters settings

V-STATS™ PC Software application combines and includes relevant features of the predicate Score Software and of the Oxinet III Software. In particular these are:

A. Downloading, analyzing, reporting trend data
- equivalent or similar method to download trend data stored in monitor's internal memory
- equivalent or similar trend data display, event markers, scrolling and zooming functions
- equivalent or similar operator-adjustable data analysis criteria
- equivalent or similar printable report

B. Remote Monitoring and Alarm Surveillance
- equivalent or similar central station (a PC running the respective software)
- equivalent or similar method to establish/control data communication between central station and multiple monitors
- equivalent or similar method to administer patients (admit/transfer/discharge a patient)
- equivalent or similar information provided in monitoring cell/window of an individual patient
- equivalent or similar alarm system

Non-Clinical Performance data [807.92(b)(1)]:

Standards Testing (Electrical, Mechanical and Environmental)
The SenTec Digital Monitoring System was tested to applicable standards for medical device Electrical Safety, Electromagnetic Compatibility, Shock and Vibration, and Environmental Temperature and Humidity. Additionally the device was tested in accordance with applicable alarm standards as well as FDA Guidance Documents and particular standards applicable for pulse oximeters and cutaneous PCO2 monitors.

Biocompatibility Testing
Biocompatibility testing has been conducted for all patient contact materials in compliance with ISO 10993-1:2003. All materials met Biocompatibility requirements.

Risk Analysis
Detailed risk, hazard, and failure analyses were performed on the SenTec Digital Monitoring System in consideration of the additions and modifications being introduced with this new 510(k). All hazards were mitigated to ALARP levels (as low as reasonably possible) and residual risks were determined to be acceptable.

Software Development and Testing
The SenTec Digital Monitoring System software was developed in accordance with FDA guidelines for MODERATE level of concern devices. The software was verified to requirements and validated to meet the specified intended use(s).

Bench Performance testing
Bench performance testing verified that the SenTec Digital Monitoring System measures pulse rate values within specified accuracy claims for all supported sensor types.

Clinical Performance data [807.92(b)(2)]:

Clinical studies were performed using the SenTec Digital Monitoring System with healthy adult volunteer subjects who were subjected to progressive induced hypoxia against arterial hemoglobin oxygen saturation determined from arterial blood samples with a CO-Oximeter as reference. The results from the clinical studies show for all supported sensors and claimed monitoring sites that the reported saturation values from the SDMS meet specified accuracy requirements.

Conclusion [807.92(b)(3)]:

The results of all **laboratory tests** demonstrate that the SenTec Digital Monitoring System meets specified requirements.

The clinical and non-clinical testing performed demonstrates that the SenTec Digital Monitoring System is safe, effective and performs as well as the predicate devices, and therefore, it is substantial equivalent to the predicate devices.

Other information [807.92(d)]:

Not applicable.

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

SENTEC AG
C/O Mr. Stephen H. Gorski
IMAGENIX, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

DEC - 3 2010

Re: K101690
Trade/Device Name: SenTec Digital Monitoring System (SDMS)
Regulation Number: 21 CFR 868.2480
Regulation Name: Cutaneous Carbon Dioxide ($PcCO^2$) monitor
Regulatory Class: II
Product Code: LKD, DQA, DPZ
Dated: November 23, 2010
Received: November 24, 2010

Dear Mr. Gorski:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): DEC - 3 2010

Device Name: SenTec Digital Monitoring System (SDMS)

Indications for use:

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Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ____X____ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) L Scheller
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101690