K071672



# Section 5 – Summary of Safety & Effectiveness

SEP 12 2007

## 510(k) Summary

**Submitter** [807.92(a)(1)]:

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**Contact Person** [807.92(a)(1)]: **Ms. Sabine Nieba, Ph.D.**
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**Date prepared** [807.92(a)(1)]: **August 18, 2007**

**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** SenTec Digital Monitor, V-Sign™ Sensor & Accessories for sensor application/maintenance; new Multi-Site Attachment Rings | 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 |
|---|---|---|---|
| K041548 | 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. |
| K063434 | TOSCA 500 tcPCO2, SpO2 and PR monitoring system | Radiometer Basel AG | These devices are predicate for PCO2 only monitoring using the new *Multi-Site Attachment Ring* to attach the V-Sign Sensor to the patient.<br><br>The "TOSCA Fixation Ring 32 mm" cleared in K063434 is predicate for the usage of the *Multi-Site Attachment Ring* in adult and pediatric patients.<br><br>The "Adhesive Ring 32 mm" cleared in K991644 is predicate for the usage of the *Multi-Site Attachment Ring* in neonates. |
| K991644 | MicroGas 7650 Transcutaneous Monitor | Linde Medical Sensors | |

**Reason For Submission:** Additional or Expanded Indications

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

The SenTec Digital Monitoring System (SDMS) is a device consisting of a stand-alone monitor, a digital sensor, a connecting cable, 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 a single, digital sensor (V-Sign™ Sensor) applied to the ear lobe with the SenTec Ear Clip.

This new 510(k) adds two new Multi-Site Attachment Rings for PCO2 monitoring only, applied to a conventional PCO2 measurement site:

- MAR-A/P/N for adult, pediatric and neonatal patients
- MAR-A/P for adult and pediatric patients

The monitoring features of the SDMS are unchanged

The Multi-Site Attachment Rings consists of a round adhesive pad integrated with a snap ring. The adhesive pad attaches to the patient's skin at the measurement site and the snap ring captures the V-Sign™ Sensor while permitting rotation and removal/reinsertion of the sensor. The ring is prepared for application by removing an adhesive liner film.

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

The SenTec Digital Monitoring System – consisting of the *SenTec Digital Monitor (SDM), the V-Sign™ Sensor* 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.

The *V-Sign™ Sensor*, model VS-A/P, is 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 the *V-Sign™ Sensor* is indicated for carbon dioxide tension monitoring only.

SenTec's *Ear Clip*, model EC-A/P, is intended for use with the *V-Sign™ Sensor* 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 the *V-Sign™ Sensor* 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 Ring*, model MAR-A/P/N, is intended for use with the *V-Sign™ Sensor* when continuous, non-invasive carbon dioxide tension monitoring is required for adult pediatric, and neonatal patients. The *Multi-Site Attachment Ring*, model MAR-A/P/N, is for single use and is indicated to attach the *V-Sign™ Sensor* to conventional measurement sites for carbon dioxide tension monitoring.

SenTec's *Multi-Site Attachment Ring*, model MAR-A/P, is intended for use with the *V-Sign™ Sensor* when continuous, non-invasive carbon dioxide tension monitoring is required for adult and pediatric patients. The *Multi-Site Attachment Ring*, model MAR-A/P, is for single use and is indicated to attach the *V-Sign™ Sensor* to conventional measurement sites for carbon dioxide tension monitoring.

## Comparison to predicate device [807.92(a)(6)]:

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

The new Multi-Site Attachment Rings are to be used only for $PCO_2$ measurements. All relevant features of the SenTec Digital Monitoring System are equivalent to the TOSCA 500 as well as to the PCO2-part of the Microgas 7650. The key features are:

- same principles of operation (2 wavelength $SpO_2$ measurement, and $PCO_2$ electrode technology)
- sensors heated to typically 42 °C (note SDMS uses 41°C for neonatal applications)
- equivalent or similar means to control sensor temperature and application time at the site
- equivalent or similar sensor application means [adhesive Ear Clip and adhesive attachment rings]
- equivalent or similar sensor calibration unit integrated in monitor
- equivalent or similar alarms, messages and menu structure as predicate devices
- equivalent or similar accessories for maintenance: membrane exchange tool, sensor contact gel, service gas

The method of operation is equivalent to that of the SenTec Digital Monitoring System listed under K041548, in particular for sensor preparation and monitoring.

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

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

Detailed risk, hazard, and failure analyses were performed on the SDMS in consideration of the Multi-Site Attachment Rings. All hazards were mitigated to ALARP levels (as low as reasonably possible) and residual risks were determined to be acceptable.

Application tests performed with the V-Sign Sensor and Multi-Site Attachment Rings confirmed that the sensor was properly positioned for measurement of PCO2.

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

In consideration of the Guidance Document for Cutaneous Carbon Dioxide Monitors no additional Clinical studies were required and none were performed.

## Conclusion [807.92(b)(3)]:

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

As described above, the SenTec Digital Monitoring System with Multi-Site Attachment Rings performs in a manner equivalent to the predicate devices. Device safety is substantiated by risk analyses and biocompatibility of patient contact materials.

## Other information [807.92(d)]:

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2007

SenTec AG
C/O Mr. Stephen H. Gorski
Submission Correspondent for SenTec AG
Imagenix, Incorporated
S65 West 35739 Piper Road
Eagle, Wisconsin 53119

Re: K071672
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
Dated: May 21, 2007
Received: June 19, 2007

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.

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

# Indications for Use

**510(k) Number** (if known):

**Device Name:** SenTec Digital Monitoring System (SDMS)

**Indications for use:**

The SenTec Digital Monitoring System – consisting of the *SenTec Digital Monitor (SDM), the V-Sign™ Sensor* 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.

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) [signature]
Division of Anesthesiology, General Hospital 9/10/07
Infection Control, Dental Devices

510(k) Number: K071672