



Food and Drug Administration
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December 17, 2015

SenTec AG
% Mr. Stephen Gorski
Regulatory Consultant
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, WI 53119

Re: K151329
Trade/Device Name: SenTec Digital Monitoring System (SDMS)
Regulation Number: 21 CFR 868.2480
Regulation Name: Cutaneous carbon dioxide (PcCO₂) monitor
Regulatory Class: Class II
Product Code: LKD, DPZ, DQA, KLK, LPP
Dated: November 22, 2015
Received: November 24, 2015

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151329

Device Name
SenTec Digital Monitoring System (SDMS)

Indications for Use (Describe)

The SenTec Digital Monitoring System – consisting of the SenTec Digital Monitor (SDM), Sensors and Accessories – is indicated for continuous, noninvasive patient monitoring. The SenTec Digital Monitoring System is indicated for use in clinical and non-clinical settings such as hospitals, hospital-type facilities, intra-hospital transport environments, clinics, physician offices, ambulatory surgery centers and – if under clinical supervision– home environments. The SenTec Digital Monitoring System is for prescription use only.

The V-Sign Sensor 2, model VS-A/P/N, is indicated for use with the SenTec Digital Monitor when continuous, noninvasive 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 2 is indicated for carbon dioxide tension monitoring only.

The OxiVenT Sensor, model OV-A/P/N, is indicated for use with the SenTec Digital Monitor when continuous, noninvasive monitoring of carbon dioxide tension and oxygen tension as well as oxygen saturation and pulse rate are required for adult and pediatric patients. In neonatal patients the use of OxiVenT Sensor is indicated for carbon dioxide and oxygen tension monitoring only. Oxygen tension monitoring is contraindicated for patients under gas anesthesia.

SenTec's Ear Clip, model EC-MI, is intended for use with the V-Sign Sensor 2 when continuous, noninvasive carbon dioxide tension, oxygen saturation and pulse rate monitoring and with the OxiVenT Sensor when continuous, noninvasive carbon dioxide and oxygen tension monitoring as well as 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 2 or OxiVenT Sensor to the earlobe of the patient. The use of the Ear Clip is contraindicated for patients whose earlobes 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 2 to conventional measurement sites for carbon dioxide tension monitoring when continuous, noninvasive carbon dioxide tension monitoring is required for adult, pediatric, and neonatal patients. The Multi-Site Attachment Rings, model MAR-SF and model MAR-MI, are intended to attach the OxiVenT Sensor to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, noninvasive carbon dioxide and/or oxygen tension monitoring is required for adult, pediatric, and neonatal patients. If oxygen saturation and pulse rate monitoring are (additionally) required in adult and pediatric patients the Multi-Site Attachment Rings, model MAR-SF and model MAR-MI, are intended to attach the V-Sign Sensor 2 or the OxiVenT Sensor to the forehead, cheek, upper arm as well as on the back above the shoulder blade. The Multi-Site Attachment Rings, model MAR-SF and model MAR-MI, are for single use.

SenTec's Staysite Adhesive pad for MAR, model SA-MAR, is an optional, single-use adhesive pad which is indicated for use with Multi-Site Attachment Rings, models MAR-MI and MAR-SF, if more secure attachment is required. The Staysite Adhesive pad for MAR, model SA-MAR, is for single use.

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 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter [807.92(a)(1)]:

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Contact Person [807.92(a)(1)]:

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Date prepared [807.92(a)(1)]:

Dec 14th, 2015

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	LKD	II	21 CFR Part 868.2480
	Cutaneous Oxygen Monitor	Monitor, oxygen, cutaneous, for infant not under gas anesthesia	KLK	II	21 CFR Part 868.2500
	Cutaneous Oxygen Monitor	Monitor, oxygen, cutaneous, for uses other than for infant not under gas anesthesia	LPP	II	21 CFR Part 868.2500
	Pulse Oximeter	Oximeter	DQA	II	21 CFR Part 870.2700
	Pulse Oximeter	Oximeter, Ear	DPZ	II	21 CFR Part 870.2710

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

	Device	Manufacturer	Comment
K101690	SenTec Digital Monitoring System	SenTec AG	This device is predicate for PCO ₂ , SpO ₂ , and PR monitoring for monitoring of PCO ₂ , SpO ₂ , and PR at the ear lobe, forehead and cheek in adult and pediatric patients and for PCO ₂ monitoring only in adult, pediatric and neonatal patients using conventional PCO ₂ measurement sites.
K093154	TCM CombIM	Radiometer	This device is the predicate for PO ₂ monitoring on conventional PO ₂ monitoring sites in adult and through neonatal patients.
K101690	V-STATS™ PC software V3.00	SenTec AG	The V-STATS™ software V3.00 (including the V-CareNeT remote monitoring package) is predicate for trend reporting, data analysis and remote monitoring of the SenTec Digital Monitor using the current V-STATS V4.00, which includes the new PO ₂ monitoring parameter.

Reason For Submission: Additional or Expanded Indications**Description of the device** [807.92(a)(4)]:

The SenTec Digital Monitoring System (SDMS) as listed under K101690 is a device consisting of a stand-alone monitor [SenTec Digital Monitor (SDM)], the digital sensors V-Sign™ Sensor (model VS-A/P) and its successor V-Sign™ Sensor 2 (model VS-A/P/N), 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, forehead or cheek 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. V-STATS™ is an optional PC software application for remote monitoring and/or trend reporting and statistical analysis of the data measured with the SDMS.

The additions and expanded indications of the **SenTec Digital Monitoring System (SDMS)** introduced by this new 510(k) submission are summarized below:

- This new 510(k) submission **expands the intended use of the SDMS by introducing non-invasive, transcutaneous oxygen (tcPO₂)** by measuring the oxygen partial pressure (PO₂) as new monitoring parameter to the SDMS. Introducing the tcPO₂ parameter includes updated firmware versions of the existing SenTec Digital Monitor (SDM) and the introduction of a new digital sensor (OxiVenT™ Sensor, see below).
- This new 510(k) submission **introduces SenTec's OxiVenT™ Sensor, model OV-A/P/N**. The OxiVenT™ Sensor is a combined sensor for the continuous measurement of transcutaneous oxygen (tcPO₂), as well as the previously cleared measurement of transcutaneous carbon dioxide (tcPCO₂), oxygen saturation (SpO₂) and pulse rate (PR).
- V-Sign™ Sensor 2 (model VS-A/P/N) has been cleared under **K101690**. This new 510(k) submission **expands the intended use by introducing new SpO₂/PR measurement sites** in adult and pediatric patients: Next to the already existing measurement sites on the forehead and cheek, new the upper arm and area on the back above the shoulder blade are added.
- This new 510(k) submission **expands the intended use of the Multi-Site Attachment Rings**, models MAR-MI and MAR-SF, approved under **K101690** and **K071672**, to attach the new OxiVenT™ Sensor to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, noninvasive carbon dioxide and/or oxygen tension monitoring is required for adult, pediatric, and neonatal patients. If oxygen saturation and pulse rate monitoring are (additionally) required in adult and pediatric patients the Multi-Site Attachment Rings, model MAR-SF and model MAR-MI, are intended to attach the V-Sign™ Sensor 2 or the new OxiVenT™ Sensor to the forehead, cheek, as well as the new pulse oximetry (SpO₂/PR) measurement sites upper arm as well as on the shoulder blade.
- This new 510(k) submission introduces the Staysite™ Adhesive pad (REF SA-MAR), an additional adhesive pad that can be used optionally if more secure attachment is required – the pad is attached on top off the Multi-Site Attachment Rings (MAR-SF/MI).
- The **V-STATS™ PC software** for trend data reporting and remote monitoring (cleared in **K101690**) has been updated to version 4.00 in order to incorporate download and display of the new PO₂ parameter.

In total, the modifications, additions, and enhancements described above represent the step-wise evolution of the SenTec Digital Monitoring System (SDMS) to provide improved monitoring as well as expanded measurement and reporting capabilities. A traditional 510(k) has been selected instead of a special 510(k) because some of the changes affect the indications for use.

Indications for Use [807.92(a)(5)]:

The *SenTec Digital Monitoring System (SDMS)* – consisting of the *SenTec Digital Monitor (SDM)*, sensors and accessories – is indicated for continuous, noninvasive patient monitoring. The *SenTec Digital Monitoring System* is indicated for use in clinical and non-clinical settings such as hospitals, hospital-type facilities, intra-hospital transport environments, clinics, physician offices, ambulatory surgery centers and – if under clinical supervision – home environments. The *SenTec Digital Monitoring System* is for prescription use only.

The *V-Sign™ Sensor 2*, model VS-A/P/N, is indicated for use with the *SenTec Digital Monitor* when continuous, noninvasive 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 2* is indicated for carbon dioxide tension monitoring only.

The *OxiVenT™ Sensor*, model OV-A/P/N, is indicated for use with the *SenTec Digital Monitor* when continuous, noninvasive monitoring of carbon dioxide tension and oxygen tension as well as oxygen saturation and pulse rate are required for adult and pediatric patients. In neonatal patients the use of *OxiVenT™ Sensor* is indicated for carbon dioxide and oxygen tension monitoring only. Oxygen tension monitoring is contraindicated for patients under gas anesthesia.

SenTec's *Ear Clip*, model EC-MI, is intended for use with the *V-Sign™ Sensor 2* when continuous, noninvasive carbon dioxide tension, oxygen saturation and pulse rate monitoring and with the *OxiVenT™ Sensor* when continuous, noninvasive carbon dioxide and oxygen tension monitoring as well as oxygen saturation and pulse rate monitoring are required. The *Ear Clip* is for single use and is indicated to attach the *V-Sign™ Sensor 2* or *OxiVenT™ Sensor* to the earlobe of the patient. The use of the *Ear Clip* is contraindicated for patients whose earlobes 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 2* to conventional measurement sites for carbon dioxide tension monitoring when continuous, noninvasive carbon dioxide tension monitoring is required for adult, pediatric, and neonatal patients. The *Multi-Site Attachment Rings*, model MAR-SF and model MAR-MI, are intended to attach the *OxiVenT™ Sensor* to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, noninvasive carbon dioxide and/or oxygen tension monitoring is required for adult, pediatric, and neonatal patients. If oxygen saturation and pulse rate monitoring are (additionally) required in adult and pediatric patients the *Multi-Site Attachment Rings*, model MAR-SF and model MAR-MI, are intended to attach the *V-Sign™ Sensor 2* or the *OxiVenT™ Sensor* to the forehead, cheek, upper arm as well as on the shoulder blade. The *Multi-Site Attachment Rings*, model MAR-SF and model MAR-MI, are for single use.

SenTec's *Staysite™ Adhesive pad*, model SA-MAR, is an optional, single use adhesive pad which is indicated for use with *Multi-Site Attachment Rings*, models MAR-MI and MAR-SF if more secure attachment is required. The *Staysite™ Adhesive pad* for MAR, model SA-MAR, is for single use.

V-STATS™ is a 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 (SDMS) 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 K101690 the technological characteristics (hardware and software) regarding continuous, noninvasive patient monitoring of PCO₂, SpO₂ and PR remain unchanged are identical to the SDMS configuration listed under K101690.

In this submission the intended use of the SDMS has been extended to include additionally continuous, noninvasive monitoring of PO₂. This addition required hardware (e.g. new sensor type) and software (firmware and V-STATS™ PC software) changes. All relevant patient monitoring features of the SDMS for PO₂ monitoring are equivalent to those of Radiometer`s TCM CombiM when used with the tc Sensor 84 as cleared in K093154

SenTec`s new OxiVenT™ Sensor (model OV-A/P/N) uses the exact same basic principles of operation and the same technology as the predicate devices. The OxiVenT™ Sensor uses a different PO₂ monitoring technology than its predicate device (Radiometer`s TCM CombiM with tc Sensor 84, K093154) but with equivalent function. This does not raise additional issues regarding safety and effectiveness.

The V-Sign™ Sensor 2 (model VS-A/P/N) in this submission uses the exact same basic principles of operation and the same technology as cleared in K101690. However, additional pulse oximetry monitoring sites in adult and pediatric patients were added in this submission. Also, the lowest operator-selectable sensor set temperature is new 37°C instead of 39°C previously. These differences do not raise additional issues regarding safety and effectiveness.

The existing accessories (Digital Sensor Adapter Cable, Ear Clip, Multi-Site Attachment Rings, Membrane Changer, Service Gas, Contact Gel) remain unchanged but may now also be used for SenTec`s new OxiVenT™ Sensor (model OV-A/P/N) (subject to this submission). The new, optional sensor application accessory, Staysite™ Adhesive pad (model SA-MAR), does not add new indications and does not raise additional issues regarding safety and effectiveness.

The latest version of the V-STATS™ PC software including the V-CareNet™ package (this submission) remains unchanged in function as cleared in K101690 regarding remote monitoring and/or trend reporting and statistical data analysis. In this submission data download, display and statistical analysis of the new PO₂ monitoring parameter has been added.

Comparison of Technological Features to Predicate Devices:

Claim / Attribute	Modified Device (Applicant) SDMS with OxiVenT™ Sensor or V-Sign™ Sensor 2	Predicate Device SDMS with V-Sign™ 2 Sensor	Predicate Device TCM CombiM with tc Sensor 84
Manufacturer	SenTec AG	SenTec AG	Radiometer Medical ApS
Covered by K-Number	To be assigned	K101690	K093154
Monitor	'SenTec Digital Monitor' (SDM) (SMB V08.00 and MPB V06.00)	'SenTec Digital Monitor' (SDM) (SMB V07.00 and MPB V05.00)	TCM CombiM monitor

Claim / Attribute	Modified Device (Applicant) SDMS with OxiVent™ Sensor or V-Sign™ Sensor 2	Predicate Device SDMS with V-Sign™ 2 Sensor	Predicate Device TCM CombiM with tc Sensor 84
Sensors considered in comparison	V-Sign™ Sensor 2 (VS-A/P/N): PCO ₂ , SpO ₂ , PR OxiVent™ Sensor (OV-A/P/N): PCO ₂ , PO ₂ , SpO ₂ , PR	V-Sign™ Sensor 2 (VS-A/P/N): PCO ₂ , SpO ₂ , PR	tc Sensor 84: PCO ₂ , PO ₂ ,
Patient Population	Adults, Pediatrics for PCO ₂ , PO ₂ , SpO ₂ , PR monitoring. Adults, Pediatrics, Neonates for PCO ₂ , PO ₂ monitoring.	Adults, Pediatrics for PCO ₂ , SpO ₂ , PR monitoring. Adults, Pediatrics, Neonates for PCO ₂ -only monitoring.	Adults, Pediatrics, Neonates for PCO ₂ , PO ₂ monitoring.
Intended Use (monitoring system)	The SenTec Digital Monitoring System – consisting of the SenTec Digital Monitor (SDM), sensors and accessories - is indicated for continuous, noninvasive patient monitoring.	The SenTec Digital Monitoring System – consisting of the SenTec Digital Monitor (SDM), sensors and accessories - is indicated for continuous, noninvasive patient monitoring.	The TCM CombiM monitoring system is intended for continuous transcutaneous monitoring of carbon dioxide (tcpCO ₂) and oxygen (tcpO ₂) partial pressures.
SpO ₂ range	1 – 100%	1 – 100%	N/A
SpO ₂ Accuracy	For all approved sites: V-Sign™ Sensor 2: 70 – 100%: ± 2% (Arms) OxiVent™ Sensor: 70 – 100%: ± 2.25% (Arms) < 70%: unspecified	For all approved sites: V-Sign™ Sensor 2: 70 – 100%: ± 2% (Arms) < 70%: unspecified	N/A
PR range	30 – 250 bpm	30 – 250 bpm	N/A
PR Accuracy	± 3 bpm	± 3 bpm	N/A
PCO ₂ range	0 – 200 mmHg (0 – 26.7 kPa)	0 – 200 mmHg (0 – 26.7 kPa)	5-200 mmHg (0.7-26.7 kPa)
PCO ₂ Drift	typically < 0.5%/h	typically < 0.5%/h	≤ 1 %/h
PCO ₂ Response time	V-Sign™ Sensor 2: typically < 75 s OxiVent™ Sensor:: typically < 80 s	V-Sign™ Sensor 2: typically < 75 s	≤ 60 sec
PCO ₂ Linearity	typically < 1.0 mmHg (0.13 kPa)	< 1.0 mmHg (0.13 kPa)	at 1 % CO ₂ : better than 1 mmHg (0.13 kPa) at 10 % CO ₂ : better than 1 mmHg (0.13 kPa) at 33 % CO ₂ : better than 5 mmHg (0.67 kPa)
PO ₂ range	0 – 800 mmHg (0 – 106.7 kPa)	N/A	0 – 800 mmHg (0.0 – 99.9 kPa)
PO ₂ Drift	< 0.1%/h	N/A	≤ 1 %/h
PO ₂ Response time	< 120 s	N/A	≤ 25 sec
Alarm System	Physiological and technical alarms. Auditory and visual alarm singals.	Physiological and technical alarms.	Physiological and technical alarms.

Claim / Attribute	Modified Device (Applicant) SDMS with OxiVenT™ Sensor or V-Sign™ Sensor 2	Predicate Device SDMS with V-Sign™ 2 Sensor	Predicate Device TCM CombiM with tc Sensor 84
PO2 Linearity	< 1 mmHg (0.1 kPa)	N/A	at 0 % O2: better than 1 mmHg (0.13 kPa) at 21 % O2: better than 3 mmHg (0.4 kPa) at 50 % O2: better than 5 mmHg (0.67 kPa) at 90 % O2: better than 25 mmHg (3.33 kPa)

Claim / Attribute	New Device (Applicant) V-STATS™ V4.00 (incl. V-CareNeT™ Package)	Predicate Device V-STATS™ V3.00 (incl. V-CareNeT™ Package)
Manufacturer	SenTec AG	SenTec AG
Covered by K-Number	(To be assigned)	K101690
Brand Name	V-STATS™ Software (incl. V-CareNeT™ Package)	V-STATS™ Software (incl. V-CareNeT™ Package)
Supported device	SDM with OxiVenT™ Sensor or SDM with V-Sign™ Sensor	SDM with V-Sign™ Sensor 2
Intended Use	V-STATS™ is a PC-based software which is intended 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.	V-STATS™ is a PC-based software which is intended 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.
Required System Components	<p>Trend Data Download from SenTec Digital Monitor (SDM) via serial interface</p> <ul style="list-style-type: none"> • PC with V-STATS 4.00 • SDM with SMB-SW-V07.01 or higher • conventional serial cable to connect SDM to PC with V-STATS <p>Trend Data Download from SDM via LAN interface (network)</p> <ul style="list-style-type: none"> • PC with V-STATS 4.00, V-CareNeT Package must be activated • SDM with SMB-SW-V07.01 or higher • local-area network (LAN) with router / switch <p>Operating system: Microsoft Windows XP (32 bits), Vista (32 and 64 bits), 7 (32 and 64 bits), 8 (32 and 64 bits), 8.1 (32 and 64 bits)</p>	<p>Trend Data Download from SenTec Digital Monitor (SDM) via serial interface</p> <ul style="list-style-type: none"> • PC with V-STATS 3.00 • SDM with SMB-SW-V06.10 or newer • conventional serial cable to connect SDM to PC with V-STATS <p>Trend Data Download from SDM via LAN interface (network)</p> <ul style="list-style-type: none"> • PC with V-STATS 3.00, V-CareNeT Package must be activated • SDM with SMB-SW-V07.00 • local-area network (LAN) with router / switch <p>Operating system: Microsoft Windows XP, Vista</p>
Basic Menu functions	Data import/export, trend curve display, data analysis (e.g. event markers, set baseline, statistical analysis), create analysis report, system setting, help menu (incl. searchable online help), remote monitoring	Data import/export, trend curve display, data analysis (e.g. event markers, set baseline, statistical analysis), create analysis report, system setting, help menu, remote monitoring
Parameters displayed	PCO2, PO2, SpO2, PR, PI (pulsation index), HP (heating power)	PCO2, SpO2, PR
Data presentation options	Trend curves, statistical analysis, customized analysis reports for print-out or pfd	Trend curves, statistical analysis, customized analysis reports for print-out
Remote monitoring option	V-CareNeT™ included	V-CareNeT™ included

Non-Clinical Performance data [807.92(b)(1)]:**Standards Testing** (Electrical, Mechanical and Environmental)

The SenTec Digital Monitoring System (SDMS) 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, PO₂ monitors.

Biocompatibility Testing

Biocompatibility testing has been conducted for all patient contact materials in compliance with ISO 10993-1:2009. Scope of testing addressed the new/changed materials of the V-Sign™ Sensor 2 and OxiVenT™ Sensor, as well as the new Staysite™ Adhesive pad. Testing included cytotoxicity, sensitization and irritation, consistent for the specified use with intact skin. Results of testing indicate the materials were non-cytotoxic, non-irritant, and did not elicit a sensitization response. All materials met Biocompatibility requirements.

Risk Analysis

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

Software Development and Testing

The SenTec Digital Monitoring System (SDMS) 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 (SDMS) 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 (SDMS) 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 (SDMS) meets specified requirements.

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

Other information [807.92(d)]:

Not applicable.