May 17, 2024

Sentec AG
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K232516
Trade/Device Name: Sentec Digital Monitoring System (SDMS) tCOM+
Regulation Number: 21 CFR 868.2480
Regulation Name: Cutaneous Carbon Dioxide (Pcco2) Monitor
Regulatory Class: Class II
Product Code: LKD, KLK, LPP, DQA, DPZ
Dated: April 16, 2024
Received: April 17, 2024

Dear Paul Dryden:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232516

Device Name
Sentec Digital Monitoring System (SDMS)

Indications for Use *(Describe)*

The Sentec Digital Monitoring System (SDMS) - consisting of monitors, sensors, cables, accessories and disposables for sensor application/maintenance and PC-based software - is indicated for non-invasive patient monitoring of oxygenation and ventilation.

Note: This manual uses the term "system" to refer to any combination of the tCOM+ or SDM and sensors, cables, accessories, disposables, and software.

The Sentec Digital Monitoring System is for prescription use only. Devices are non-sterile and non-invasive.

The monitor is not in direct contact with the patient during monitoring. The V-Sign™ Sensor 2, the OxiVenT™ Sensor, the Ear Clip, the Multi-Site Attachment Rings, the Non-Adhesive Wrap, the Staysite™ Adhesive and the Contact Gel are in contact with the intact skin of the patient during monitoring.

Intended patient population: tcPCO2 and tcPO2 monitoring is indicated in adult/pediatric (older than term birth plus 12 months) and neonatal (younger than term birth plus 12 months) patients. Pulse oximetry monitoring is indicated in adult/pediatric patients only.

The target user population: of the Sentec Digital Monitoring System (SDMS) is professional medical personnel, e.g. nurses, physicians, and - if under clinical supervision - lay operators. The correct and safe application of tcPCO2 and tcPO2 measuring equipment require straining of the user (e.g. physiological restrictions, technical aspects such as membrane change, meaning of drift, calibration). Home care providers also require specific training to be allowed to install the SDMS in home environments and to instruct lay persons how to apply the sensors correctly. The lay operator can-not modify the tCOM+ configuration by means of its menu.

Training: Professional medical personnel and instructed home care personnel are trained by Sentec or a qualified and authorized distributor. The instructed home care personnel provide the lay user with the lay user manual and explains attachment and detachment of the sensor. The instructed home care personnel also define the application site for the attachment of the sensor.

Environment of 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. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital type facilities typically cover facilities such as surgical centers, special nursing facilities and sleep labs out-side of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facilities.
The SDMS fulfills the requirements of a non-transit operable and portable device to be used in home environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared: 17-May-2024

510(k) Summary

1 Sponsor

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Sponsor Contact:
Caroline Möller, Ph.D., Global Head of Regulatory Affairs and Quality Assurance

Submission Contact: Paul Dryden, ProMedic Consulting LLC

2 Device

Proprietary or Trade name
Sentec Digital Monitoring System (SDMS) with tCOM+

Common/Usual Name
Transcutaneous blood gas monitoring system

Classification CFR
21 CFR §868.2480
21 CFR §868.2500
21 CFR §868.2700
21 CFR §868.2710

Product codes
LKD - Monitor, Carbon-Dioxide, Cutaneous
KLK - Monitor, oxygen, cutaneous, for infant not under gas anesthesia
LPP - Monitor, oxygen, cutaneous, for uses other than for infant not under gas anesthesia
DQA – Oximeter
DPZ- Oximeter, Ear

Predicate 510(k)s:
Sentec Digital Monitoring System (SDMS) with SDM
K041548, K071672, K101690, K151329.

Reason for Submission: Introduction of the new patient monitor tCOM+ and its accessories for the previously cleared Sentec Digital Monitoring System. The tCOM+ is the successor monitor of Sentec's

Digital Monitor (SDM). The tCOM+ monitor comprises the same features as the predicate monitor SDM but has an updated user interface controllable via touchscreen and wireless communication interfaces.

3 Device Description

Sentec's Digital Monitoring System is intended for the continuous and noninvasive monitoring of cutaneous carbon dioxide partial pressure (PCO_2), cutaneous oxygen partial pressure (PO_2), oxygen saturation (SpO_2) and pulse rate (PR) in adult and pediatric patients as well as for PCO_2 and PO_2 monitoring in neonatal patients.

The introduction of the new patient monitor tCOM+ as part of Sentec's Digital Monitoring System does not change the indications for use nor the intended patient population.

Compared to Sentec's Digital Monitoring System configuration cleared under K151329, the technological characteristics (hardware and software) regarding continuous, noninvasive patient monitoring of PCO_2, PO_2, SpO_2 and PR remain unchanged and are identical to the configuration listed under K151329.

The tCOM+ (REF 103164) is a portable, lightweight, stand-alone monitor with a convenient carrying handle and with an integrated calibration and storage facility for the V-Sign™ Sensor 2 or OxiVenT™ Sensor, respectively. It provides continuous and noninvasive PCO_2, SpO_2 and PR monitoring if used with a V-Sign™ Sensor 2 or PCO_2, PO_2, SpO_2 and PR monitoring if used with a OxiVenT™ Sensor.

4 Indications for Use

The Sentec Digital Monitoring System (SDMS) – consisting of a patient monitor, sensors, cables, accessories and disposables for sensor application/maintenance and PC-based software – is indicated for non-invasive patient monitoring of oxygenation and ventilation.

The Sentec Digital Monitoring System is for prescription use only. Devices are non-sterile and non-invasive.

The monitor is not in direct contact with the patient during monitoring. The V-Sign™ Sensor 2, the OxiVenT™ Sensor, the Ear Clip, the Multi-Site Attachment Rings, the Non-Adhesive Wrap, the Staysite™ Adhesive and the Contact Gel are in contact with the intact skin of the patient during monitoring.

Intended patient population: $tcPCO_2$ and $tcPO_2$ monitoring is indicated in adult/pediatric (older than term birth plus 12 months) and neonatal (younger than term birth plus 12 months) patients. Pulse oximetry monitoring is indicated in adult/pediatric patients only.

The target user population: The Sentec Digital Monitoring System (SDMS) is professional medical personnel, e.g. nurses, physicians, and - if under clinical supervision - lay operators. The correct and safe application of tcPC02 and tcP02 measuring equipment requires training of the user (e.g.

physiological restrictions, technical aspects such as membrane change, meaning of drift calibration). Home care providers also require specific training to be allowed to install the SDMS in home Environments and to instruct lay persons how to apply the sensors correctly. The lay operator cannot modify the tCOM+ configuration by means of its menu.

Training: Professional medical personnel and instructed home care personnel are trained by Sentec or a qualified and authorized distributor. The instructed home care personnel provide the lay user with the lay user manual and explain attachment and detachment of the sensor. The instructed home care personnel also define the application site for the attachment of the sensor.

Environment of 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. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital type facilities typically cover facilities such as surgical centers, special nursing facilities and sleep labs outside of the hospital. Intra-hospital transport includes transport of a patient within hospitals or hospital-type facilities.

The SDMS fulfils the requirements of a non-transit operable and portable device to be used in home environments.

5 Technological Characteristics

Sentec´s new patient monitor tCOM+ uses the same basic principles of operation and similar technology as the predicate device SDM. The tCOM+ introduces technological upgrades such as an updated monitor graphical user interface controllable via touchscreen and wireless connectivity. The tCOM+ is as safe and effective as its predicate device SDM.

Some of the already cleared disposables have been updated (Membrane Changer single-use, Multi-Site Attachments Rings “easy”, Contact Gel single-use and Non-Adhesive Wrap).

The latest version of the V-STATS™ PC remains unchanged as cleared in K151329 regarding remote monitoring and/or trend reporting and statistical data analysis.

6 Comparison of Technological Characteristics and Performance with the Predicate

Table 1 compares the tCOM+ with the predicate Sentec Digital Monitor.

Table 1: Comparison of tCOM+ vs. Predicate SDM

Claim / Attribute	Subject device	Predicate Device	Comments
Brand name / Model	tCOM+ (REF 103164)	Sentec Digital Monitor (REF SDM)	N/A
Description of device	The tCOM+ is a portable, lightweight, stand-alone monitor with a convenient carrying handle and with an integrated calibration and storage facility for Sentec's digital sensors. tCOM+ provides the same features as the predicate device Sentec Digital Monitor but has a modern user interface which is controllable via touchscreen and wireless communication interfaces.	Sentec's Digital Monitor (SDM) is a portable, stand-alone monitor with an integrated calibration and storage facility for Sentec's digital sensors.	Similar
510(k)	K232516	K151339	N/A
Product codes	LKD, KLK, LPP	LKD, KLK, LPP	Identical
Regulation numbers	21 CFR Part 868.2480 21 CFR Part 868.2500	21 CFR Part 868.2480 21 CFR Part 868.2500	Identical
Prescription device	Yes	Yes	Identical
Intended patient population	$tcPCO_2$ and $tcPO_2$ monitoring is indicated in adult, pediatric and neonatal patients. Pulse oximetry monitoring is indicated in adult/pediatric patients only.	$tcPCO_2$ and $tcPO_2$ monitoring is indicated in adult, pediatric and neonatal patients. Pulse oximetry monitoring is indicated in adult/pediatric patients only.	Identical
Indication for Use	The tCOM+ is a portable stand-alone patient monitor intended for continuous, noninvasive patient monitoring of carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), functional oxygen saturation (SpO_2) and pulse rate (PR), using either	The SDM is a portable stand-alone patient monitor intended for continuous, noninvasive patient monitoring of carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), functional oxygen saturation (SpO_2) and pulse rate (PR), using either • single, digital sensor (V-Sign™ Sensor 2) for PCO_2, SpO_2 and PR measurement, OR	Identical

	• single, digital sensor (V-Sign™ Sensor 2) for PCO_2, SpO_2 and PR measurement, OR • a single, digital sensor (OxiVenT™ Sensor) for PCO_2, PO_2, SpO_2 and PR measurement PO_2 measurement with tCOM+ is only possible when used in combination with an OxiVenT™ Sensor.	• a single, digital sensor (OxiVenT™ Sensor) for PCO_2, PO_2, SpO_2 and PR measurement PO_2 measurement with SDM is only possible when used in combination with an OxiVenT™ Sensor.	
Environment of 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. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital type facilities typically cover facilities such as surgical centers, special nursing facilities and sleep labs outside of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facilities.	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. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital type facilities typically cover facilities such as surgical centers, special nursing facilities and sleep labs outside of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facilities.	Identical
Method of operation	Power is applied to the monitor. Sensor is heated, calibrated and monitor is configured (alarms etc.). Sensor applied to patient with Ear Clip or Multi-Site Attachment Rings or Non-Adhesive Wrap and using Contact Gel. The patient's SpO_2, PR, and/or PCO_2 and/or PO_2 are monitored. If monitoring continues for more than predefined time an alarm is triggered (Site Timer) and site must be inspected.	Power is applied to the monitor. Sensor is heated, calibrated and monitor is configured (alarms etc.). Sensor applied to patient with Ear Clip or Multi-Site Attachment Rings or Non-Adhesive Wrap and using Contact Gel. The patient's SpO_2, PR, and/or PCO_2 and/or PO_2 are monitored. If monitoring continues for more than predefined time an alarm is triggered (Site Timer) and site must be inspected.	Identical

	At every 8 - 12 hours, the sensor must be calibrated. Membrane must be prepared (exchanged) typically every 28 days.	At every 8 -12 hours, the sensor must be calibrated. Membrane must be prepared (exchanged) typically every 28 days.	
Physical characteristics	The tCOM+ is portable and mountable on a standard hospital rail. Height = 15.4 cm Width = 26.8 cm Depth = 16.2 cm Weight ≈ 2.5 kg	The SDM is portable and mountable on a standard hospital rail. Height = 10.2 cm Width = 27 cm Depth = 23 cm Weight ≈ 2.5 kg	Similar
Portable	Yes, handle at the top of the monitor	Yes (flip feet serves as carrying handle)	Similar
Wireless data communication	The tCOM+ enables: • Wi-Fi communication for connection to networks. • Bluetooth communication (disabled in the software for this version). • RFID communication (disabled in the software for this version).	The SDM offers no wireless data communication	Different, additional communications interface
User controls	The tCOM+ uses a touch screen to navigate between the different menus, and the power ON/STAND-BY switch is on the left-hand side of the panel.	The SDM uses buttons to navigate between the different menus, and the power ON/OFF switch is on the rear of the panel.	Different, update to touch screen User Interface
	Sensor Adapter Cable (for tCOM+)	**Digital Sensor Adapter Cable (for SDM)**	
Brand name / Model	Sensor Adapter Cable Regular (REF 103420), Long (REF 103421) and Extra Long (REF 103422)	Digital Sensor Adapter Cable 150 cm (REF AC-150), 250 cm (REF AC-250) and 750 cm (AC-750)	N/A
Device Description	Adapter cable required to connect the V-Sign™ Sensor 2 and OxiVenT™ Sensor to the tCOM+ patient monitor. It transfers the power needed to operate the sensor. It furthermore transmits digitized data between the digital sensor and the tCOM+.	Adapter cable required to connect the V-Sign™ Sensor 2 and OxiVenT™ Sensor to the Sentec Digital Monitor. It transfers the power needed to operate the sensor. It furthermore transmits digitized data between the digital sensor and the SDM.	Identical

Intended Use	Intended to connect digital Sentec sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) to the new patient monitor tCOM+.	Intended to connect digital Sentec sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) to the Sentec Digital Monitor.	Identical
	Calibration Gas (for tCOM+)	**Service Gas (for SDM)**	
Brand name / Model	Calibration Gas (REF 103149) for tCOM+	Service Gas (REF GAS-0812) for SDM	N/A
Device Description	Calibration gas for docking station, cylinder of 0.21 l at 9.5 bar. The calibration gas is needed for the periodic calibration of the V-Sign™ Sensor 2 and the OxiVenT™ Sensor.	Calibration gas for docking station, cylinder of 0.56 l at 9.5 bar. The calibration gas is needed for the periodic calibration of the V-Sign™ Sensor 2 and the OxiVenT™ Sensor.	Similar
Intended Use	The Calibration Gas serves as calibration gas for Sentec's sensors that monitor $tcPCO_2$ and/or $tcPO_2$ (V-Sign™ Sensor 2 and OxiVenT™ Sensor). The Calibration Gas is intended for use only with the docking station integrated in the tCOM+.	The Service Gas serves as calibration gas for Sentec's sensors that monitor $tcPCO_2$ and/or $tcPO_2$ (V-Sign™ Sensor 2 and OxiVenT™ Sensor). The Service Gas, is intended for use only with the docking station integrated in the Sentec Digital Monitor.	Similar
Gas composition	8-vol% CO_2, 12-vol% O_2, 80-vol% N_2 mixture	8-vol% CO_2, 12-vol% O_2, 80-vol% N_2 mixture	Identical
Container characteristics	Gas bottle of 0.21 l at a pressure of 9.5 bar (2,05 l at 1 bar, 21°C). Compliant with TRG 300; 75/324/EWG; 94/1/EG; D.O.T.-2Q; Aerosol UN 1950 or Compressed Gas UN 1956, Non- flammable gas	Gas bottle of 0.56 l at a pressure of 9.5 bar (5.7 l at 1 bar, 21 °C). Compliant with TRG 300; 75/324/EWG; 94/1/EG; D.O.T.-2Q; Aerosol UN 1950 or Compressed Gas UN 1956, Non- flammable gas.	Similar

The Table 2 hereafter compares the updated disposables with their predicates.

Table 2: New versions of Sentec's Digital Monitoring System Disposables in comparison with their Predicates

Claim / Attribute	Subject device	Predicate Device	Comments
Product codes	LKD, KLK, LPP, DQA	LKD, KLK, LPP, DQA	Identical
Regulation numbers	21 CFR Part 868.2480, 21 CFR Part 868.2500, 21 CFR Part 870.2700, 21 CFR Part 870.2710	21 CFR Part 868.2480, 21 CFR Part 868.2500, 21 CFR Part 870.2700, 21 CFR Part 870.2710	Identical
	Single Dose Contact Gel	**Contact Gel**	
Brand name / Model	Single Dose Contact Gel (REF GEL-SD)	Contact Gel (REF GEL-04)	N/A
510(k)	K232516	K041548	N/A
Description of device	Sentec's Contact Gel ensures adequate contact between the patient's skin and the sensor, i.e., CO_2/ O_2 diffusing out of the skin will be trapped by the contact liquid rather than diffusing to the surroundings.	Sentec's Contact Gel ensures adequate contact between the patient's skin and the sensor, i.e., CO_2/ O_2 diffusing out of the skin will be trapped by the contact liquid rather than diffusing to the surroundings.	Identical
Single use	Yes	No	Difference is only the packaging size
Intended Use	The Contact Gel GEL-SD serves as contact gel to achieve proper gas conduction and heat transfer between the patients' skin and Sentec's TC sensors.	The Contact Gel GEL-04 serves as contact gel to achieve proper gas conduction and heat transfer between the patients' skin and Sentec's TC sensors.	Identical
Gel Composition	(>90%) • Glycerol • 1, 2 Propanediol	(>90%) • Glycerol • 1, 2 Propanediol	Identical

	• Polyvinylpyrrolidone (PVP) low concentration • Deionized Water	• Polyvinylpyrrolidone (PVP) low concentration • Deionized Water	
Physical characteristics	Vial of 0.3 g	Bottle of 5ml	Different
Biocompatibility	Prolonged intact skin contact, compliant with ISO-10993-5 and ISO 10993-10	Prolonged intact skin contact, compliant with ISO-10993-5 and ISO 10993-10	Identical
	Membrane Changer single use	**Membrane Changer**	
Brand name / Model	Membrane changer (REF MC)	Membrane changer (REF MC-R, MC-I)	N/A
510(k)	K232516	K101690, K151339	N/A
Device Description	The Membrane Changer single-use allows for a straight-forward replacement of Sentec's Sensor Membranes. The bottom of the device has an anti-slippery coating to improve usability.	The Membrane Changer allows for a straight-forward replacement of Sentec's Sensor Membranes. The Membrane Changer reloadable (MC-R) can be reused by replacing its insert (MC-I).	Similar
Single use	Yes	No	Different
Indication for Use	The Membrane Changer serves as a tool to change the electrolyte and membrane of the V-Sign™ Sensor 2 and the OxiVenT™ Sensor.	The Membrane Changer serves as a tool to change the electrolyte and membrane of the V-Sign™ Sensor 2 and the OxiVenT™ Sensor.	Identical
	MARe-MI	**MAR-MI**	
Brand name / Model	Multi-Site Attachment Ring "Easy" Mature/Intact (REF MARe-MI)	Multi-Site Attachment Ring Mature/Intact (REF MAR-MI)	N/A
510(k)	K232516	K071672, K101690, K151339	N/A
Device Description	Single use sensor application ring, recommended for adult, pediatric and neonatal patients. The adhesive used to attach the application ring to the patient's skin is hypoallergenic, pressure sensitive and designed for medical/surgical use. The use of MARe-MI therefore is recommended for mature/intact skin applications.	Single use sensor application ring, recommended for adult, pediatric and neonatal patients. The adhesive used to attach the application ring to the patient's skin is hypoallergenic, pressure sensitive and designed for medical/surgical use. The use of MAR-MI therefore is recommended for mature/intact skin applications.	Similar

	The design of the snap ring itself has been optimized to ensure easy insertion/removal of sensors into/from the ring.		
Intended Use	Is intended to attach the Sentec sensors to conventional measurement sites. Recommended for adult, pediatric, and neonatal patients with mature/intact skin.	Is intended to attach the Sentec sensors to conventional measurement sites. Recommended for adult, pediatric, and neonatal patients with mature/intact skin.	Identical
Physical characteristics	Snap ring inner diameter = 14.65 mm Snap ring outer diameter = 20 mm Adhesive ring diameter = 30 mm Snap ring color = White Snap ring geometry = More snap joints, less wide	Snap ring inner diameter = 14.65 mm Snap ring outer diameter = 20 mm Adhesive ring diameter = 30 mm Snap ring color = Grey Snap ring geometry = Fewer snap joints, wider	Similar
Biocompatibility	Prolonged intact skin contact, compliant with ISO-10993-5 and ISO 10993-10	Prolonged intact skin contact, compliant with ISO-10993-5 and ISO 10993-10	Identical
	Non-Adhesive Wrap	**MAR-SF**	
Brand name / Model	Non-Adhesive Wrap (REF 103520)	Multi-Site Attachment Ring Sensitive/Fragile (REF MAR-SF)	N/A
510(k)	K232516	K071672, K101690, K151339	N/A
Device Description	The non-adhesive application ring, single-patient use for up to 24 hours, is recommended for preterm / neonatal patients of very low birth weight and with sensitive/fragile skin. This applicator does not contain any adhesives and is wrapped around the thigh.	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin. The adhesive making skin contact is a silicone gel adhesive used in skin therapy and wound healing. The use of MAR-SF therefore is recommended for sensitive/fragile skin applications.	Similar
Intended for Use	Is intended to be wrapped around the thigh of neonatal patients with very sensitive/fragile skin for subsequent attachment of Sentec's TC sensors.	Is intended to attach Sentec's TC sensors to conventional measurement sites, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin.	Similar
Biocompatibility	Prolonged intact skin contact, compliant with ISO-10993-5 and ISO 10993-10	Prolonged intact skin contact, compliant with ISO-10993-5 and ISO 10993-10	Identical

Physical characteristics	Snap ring inner diameter = 14.65 mm Snap ring outer diameter = 20 mm Snap ring geometry same as MARe-MI Wrap dimension: Length = 53 mm, Width = 11mm	Snap ring inner diameter = 14.65 mm Snap ring outer diameter = 20 mm Adhesive ring diameter = 30 mm	Different

7 Non-Clinical Performance data

Standards Testing

The tCOM+ was tested to applicable standards for medical devices:

- AAMI ANSI ES 60601-1: 2005 + A1: 2012 + A2: 2021 _ Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2: 2014 + A1:2020 _ Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;
- IEC 60601-1-11:2015 + A1:2020, Part 1-11 _ Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment;
- IEC 60601-2-23:2011 _ Particular requirements for the basic safety and essential performance of TC partial pressure monitoring;
- ISO 80601-2-61:2017_ Particular requirements for basic safety and essential performance of pulse oximeter equipment;
- IEC TR 60601-4-2 _ Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems;
- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 _ Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021 _ Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)];
- IEC 60601-1-11:2015 + A1:2020, Part 1-11 _ Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment;
- IEC 60601-1-6:2020 _ Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;
- IEC 60601-1-8:2020 _ Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems;

- AAMI TIR69:2017 _ Risk management of radio-frequency wireless coexistence for medical devices and systems;
- ANSI C63.27-2017 _ American National Standard for Evaluation of Wireless Coexistence.

Bench Performance Testing
Bench tests were conducted on the tCOM+ in compliance with the applicable standards for medical devices, and for mechanical strength, ingress of liquids and electronic performance. All specified requirements were met.

Biocompatibility Testing
Biocompatibility testing was conducted for all patient contact materials in compliance with ISO 10993-1:2018. All materials met Biocompatibility requirements.

Risk Management
Detailed risk, hazard, and failure analyses were performed on Sentec's Digital Monitoring System in consideration of the additions and modifications being introduced by the tCOM+ patient monitor and its accessories. All hazards were mitigated as far 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).

Human Factor Evaluation Testing
A Human Factor Evaluation testing was performed following the FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" from February 2016.

8 Clinical Performance data

No clinical performance data were generated on the tCOM+, because compared to its predicate device, the Sentec Digital Monitor (SDM), it uses the same sensors without software changes impacting algorithm or clinical performance.

The introduction of the updated disposables, the Calibration Gas for tCOM+ (103149), Multi-Site Attachment Ring "Easy" Mature/Intact (REF MARe-MI), the Non-Adhesive Wrap (REF 103520), the Contact Gel (REF GEL-SD) and the Membrane Changer single-use (REF MC), do not affect the clinical functionality or performance of Sentec's Digital Monitoring System. No further clinical data was required to support safety and performance.

The use of the devices (user interface/patient interface), use environment and indications for use remain unchanged.

9 Conclusion

The tCOM+ and its accessories are determined to be substantially equivalent to the predicate devices of the previously cleared Sentec Digital Monitoring System.

- Identical Indications for Use to the predicate devices.
- No change to patient populations.
- No change to environments of use.
- No changes to measurement modalities and related technology

The results of the laboratory tests and the Human Factors Evaluation studies demonstrate that Sentec's Digital Monitoring System with tCOM+ patient monitor, and the updated disposables meet the specified requirements.

Non-clinical testing further demonstrates that the tCOM+ patient monitor, and associated disposables are safe, effective, and substantially equivalent to the predicate Sentec Digital Monitoring System components.