July 26, 2026

Corsano Health B.V.
Peter Stas
Chief Executive Officer
Waldorpstraat 5
The Hague, CA 2521
Netherlands

Re: K261367
Trade/Device Name: Corsano CardioWatch 287-2 System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, DQA, BZG, BZQ, FLL, DRG, DXN, FRI, LEL
Dated: April 25, 2026
Received: April 27, 2026

Dear Peter STAS:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261367 ? |
|---|---|

Please provide the device trade name(s). ?

Corsano CardioWatch 287-2 System

Please provide your Indications for Use below. ?

The CardioWatch 287-2 System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of non-acutely ill patients by trained healthcare professionals.

The CardioWatch 287-2 System is intended to provide visual and audible physiologic multi-parameter alarms.

The CardioWatch 287-2 System is intended for monitoring of skin temperature at wrist of the patient or axillary temperature with connected thermometer device.

The CardioWatch 287-2 System is intended for continuous monitoring of the following physiological indices in adults (over 22years old):
• Pulse rate
• Oxygen saturation
• Skin Temperature
• Movement
• Sleep Assessment

The CardioWatch 287-2 System is intended for intermittent monitoring with the CardioWatch Bracelet of the following physiological indices in adults (over 22years old):
• Respiration rate.

The CardioWatch 287-2 System is intended for intermittent or spot-check monitoring, in adults, of:
• Non-invasive blood pressure
• Lung function & spirometry
• Weight

The CardioWatch 287-2 System is intended to monitor the activity associated with movement during sleep. The CardioWatch 287-2 System can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The CardioWatch 287-2 System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The CardioWatch 287-2 System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The CardioWatch 287-2 system is not a substitute for an ECG monitor.

| | | |
|---|---|---|
| The CardioWatch 287-2 System is not intended for SpO2 monitoring in conditions of high motion or low perfusion. | | |
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) | ? |
| Please select the age group(s) for which the device(s) is to be used. | ☐ Neonates/Newborns (Birth to < 29 days old)<br>☐ Infants (29 days old to < 2 years old)<br>☐ Children (2 years old to < 12 years old)<br>☐ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) | ? |

# Summary Safety & Effectiveness

## 1 GENERAL INFORMATION

| **Submitter and 510(k) Owner** | |
|---|---|
| Name | Corsano Health B.V. |
| Address : | Waldorpstraat 5<br>2521 CA The Hague<br>The Netherlands |
| Official Correspondent | Mr Peter STAS, CEO – Head of firm |
| Phone | +41793102442 |
| Email : | pcstas@corsano.com |
| Date of Summary : | 24th July 2026 |

| **Device Information** | |
|---|---|
| Trade/Proprietary Name | Corsano CardioWatch 287-2 System |
| Common/Usual Name | Patient Remote Monitoring System |
| Medical Specialty | Cardiovascular |
| Regulation | 870.2300 |
| Class: | II |
| Classification Name: | System, Network and Communication, Physiological Monitors |
| Product Codes: | MSX, DQA, BZG, BZQ, FLL, DRG, DXN, FRI, LEL |

Primary Product Code

| Classification Regulation | Classification Name | Device Class | Product Code | Classification Panel |
|---|---|---|---|---|
| 21 CFR 870.2300 | System, Network and Communication, Physiological Monitors | Class II | MSX | Cardiovascular |

Secondary Product Codes

| Classification Regulation | Classification Name | Device Class | Product Code | Classification Panel |
|---|---|---|---|---|
| 21 CFR 870.2700 | Oximeter | Class II | DQA | Cardiovascular |
| 21 CFR 868.1840 | Spirometer | Class II | BZG | Anesthesiology |
| 21 CFR 868.2375 | Breathing Frequency Monitor | Class II | BZQ | Anesthesiology |
| 21 CFR 870.2910 | Clinical Electronic Thermometer | Class II | FLL | General Hospital |

| Secondary Product Codes | | | | |
|---|---|---|---|---|
| Classification Regulation | Classification Name | Device Class | Product Code | Classification Panel |
| 21 CFR 870.2910 | Radiofrequency physiological signal transmitter & receiver | Class II | DRG | Cardiovascular |
| 21 CFR 870.1130 | Non-invasive Blood Pressure Monitor | Class II | DXN | Cardiovascular |
| 21 CFR 880.2700 | Stand-on Weight Scale | Class I | FRI | General Hospital |
| 21CFR 882.5050 | Sleep Assessment | Class II | LEL | Neurology |

| **Predicate Device** | |
|---|---|
| Trade/Proprietary Name | Corsano CardioWatch 287-2 System |
| 510(k) | K232548 |
| Common/Usual Name | Remote Patient Monitor |
| Medical Specialty | Cardiovascular |
| Regulation | 870.2300 |
| Class: | II |
| Classification Name: | System, Network and Communication, Physiological Monitors |
| Product Codes: | MSX, FLL, DQA, BZQ, DRG, BZG |

| **Reference Device** | |
|---|---|
| Trade/Proprietary Name | **ActiGraph CentrePoint Insight Watch** |
| 510(k) | K181077 |
| Common/Usual Name | Biofeedback device |
| Medical Specialty | Neurology |
| Regulation | 21CFR 882.5050 |
| Class: | II |
| Classification Name: | Biofeedback device |
| Product Codes: | LEL |

# 2 Device Description

The Corsano CardioWatch 287-2 System is a Remote-Patient Monitoring System that consists of a monitoring bracelet device worn on the wrist by adult patients (aged 22 years old and over), a web-based browser platform and a user mobile application operable in either Patient Mode or HealthCare Professional (HCP) Mode.

Vital signs data both on mobile devices and web-based dashboard are available to the HealthCare Provider only.

The Corsano CardioWatch 287-2 System is also integrated with third-party devices for displaying and monitoring physiological signs (spot monitoring of : non-invasive blood pressure (NIBP), lung function & spirometry (SPIRO), weight (WEIGHT) as well as continuous monitoring of axillary temperature (aTEMP).

The Corsano Bracelet is intended to continuously monitor physiological vital sign data : Pulse Rate (PR), oxygen saturation (SpO2), skin temperature (sTEMP) and activity (STEP), Sleep-Wake (SLEEP) and for intermittent monitoring of respiratory rate (RR) from the person being monitored and securely transmit the encrypted data via the Patient User App to the secure server.

The bracelet is intended for use in professional healthcare facilities, such as hospitals or skilled nursing facilities, or the home by lay users (patients) under trained healthcare professionals supervision.

The healthcare professional can securely access the patient physiological signs remotely via the Corsano mobile application HCP Mode or via a browser web-interface which are also intended to provide visual and audible physiologic multi-parameter alarms.

# 3 Intended Use / Indications for Use

The CardioWatch 287-2 System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of non-acutely ill patients by trained healthcare professionals.

The CardioWatch 287-2 System is intended to provide visual and audible physiologic multi-parameter alarms.

The CardioWatch 287-2 System is intended for monitoring of skin temperature at wrist of the patient or axillary temperature with connected thermometer device.

The CardioWatch 287-2 System is intended for continuous monitoring of the following physiological indices in adults (over 22years old):
• Pulse rate
• Oxygen saturation
• Skin Temperature
• Movement
• Sleep Assessment

The CardioWatch 287-2 System is intended for intermittent monitoring with the CardioWatch Bracelet of the following physiological indices in adults (over 22years old):
• Respiration rate.

The CardioWatch 287-2 System is intended for intermittent or spot-check monitoring, in adults, of:
• Non-invasive blood pressure
• Lung function & spirometry
• Weight

The CardioWatch 287-2 System is intended to monitor the activity associated with movement during sleep.
The CardioWatch 287-2 System can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The CardioWatch 287-2 System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The CardioWatch 287-2 System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The CardioWatch 287-2 system is not a substitute for an ECG monitor.

The CardioWatch 287-2 System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

# 4 Substantial Equivalence

The proposed device, the Corsano CardioWatch 287-2 System is identical to the Predicate Device (Corsano CardioWatch 287-2 System), in that the intended use statement remains identical with the unique addition of the sleep-wake parameter.

With respect to the Reference Device, both the devices share same intended use of Sleep-Wake assessment, intended use conditions, measurement technology, as well as in the same healthcare environments and the same intended patients.

*Technological characteristics*

Corsano CardioWatch 287-2 System share the same technological characteristics as the Reference device, providing patient sleep-assessment measurements using wearable sensors, transmit and provide data visualization to HCP's.

*Table 4-1*

| **Features** | **Proposed Device: CardioWatch 287-2 System** | **Predicate Device: CardioWatch 287-2 System** | **Reference Device: ActiGraph CentrePoint Insight Watch** | **Comment** |
|---|---|---|---|---|
| Device | Corsano Health B.V. | Corsano Health B.V. | ActiGraph, Inc. | - |

| Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: CardioWatch 287-2 System | Reference Device: ActiGraph CentrePoint Insight Watch | Comment |
|---|---|---|---|---|
| Manufacturer | | | | |
| Device Classification | II | II | II | - |
| 510(k) Number | N/A | K232548 | K181077 | - |
| Medical Specialty | Cardiovascular | Cardiovascular | Neurology | - |
| Regulation | 21 CFR 870.2300 | 21 CFR 870.2300 | 21 CFR 882.5050 | - |
| Device Classification Name | System, Network and Communication, Physiological Monitors | System, Network and Communication, Physiological Monitors | Biofeedback device | - |
| Primary Product Code | MSX | MSX | LEL | - |
| Secondary Product Code | MSX, DQA, BZG, BZQ, FLL, DRG, DXN, FRI | MSX, DQA, BZG, BZQ, FLL, DRG, DXN, FRI | - | - |
| | LEL (21 CFR 882.5050) | - | - | - |
| | | | | |
| Intended Use/ Indication for Use | The CardioWatch 287-2 System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of non-acutely ill patients by trained healthcare professionals.<br><br>The CardioWatch 287-2 System is intended to provide visual and audible physiologic multi-parameter alarms. | The CardioWatch 287-2 System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of non-acutely ill patients by trained healthcare professionals.<br><br>The CardioWatch 287-2 System is intended to provide visual and audible physiologic multi-parameter alarms. | The ActiGraph CentrePoint Insight Watch is a small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring.<br><br>The device is intended to monitor the activity associated with movement during sleep.<br>The Insight watch can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable. | Similar : the CardioWatch 287-2 remains unchanged to the Predicate Device ; the inclusion of the Reference Device intended use points have been integrated into the updated proposed Intended Use |

| Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: CardioWatch 287-2 System | Reference Device: ActiGraph CentrePoint Insight Watch | Comment |
|---|---|---|---|---|
| | The CardioWatch 287-2 System is intended for monitoring of skin temperature at wrist of the patient or axillary temperature with connected thermometer device.<br><br>The CardioWatch 287-2 System is intended for continuous monitoring of the following physiological indices in adults (over 22years old):<br>• Pulse rate<br>• Oxygen saturation<br>• Skin Temperature<br>• Movement<br>• Sleep Assessment<br><br>The CardioWatch 287-2 System is intended for intermittent monitoring with the CardioWatch Bracelet of the following physiological indices in adults (over 22years old):<br>• Respiration rate.<br><br>The CardioWatch 287-2 System is intended for intermittent or spot-check monitoring, in adults, of:<br>• Non-invasive blood pressure<br>• Lung function & spirometry<br>• Weight<br><br>The CardioWatch 287-2 System is intended to monitor the activity associated with movement during sleep. | The CardioWatch 287-2 System is intended for monitoring of skin temperature at wrist of the patient or axillary temperature with connected thermometer device.<br><br>The CardioWatch 287-2 System is intended for continuous monitoring of the following physiological indices in adults (over 22years old):<br>• Pulse rate<br>• Oxygen saturation<br>• Temperature<br>• Movement<br><br>The CardioWatch 287-2 System is intended for intermittent monitoring with the CardioWatch Bracelet of the following physiological indices in adults (over 22years old):<br>• Respiration rate.<br><br>The CardioWatch 287-2 System is intended for intermittent or spot-check monitoring, in adults, of:<br>• Non-invasive blood pressure<br>• Lung function & spirometry<br>• Weight | | |

| Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: CardioWatch 287-2 System | Reference Device: ActiGraph CentrePoint Insight Watch | Comment |
|---|---|---|---|---|
| | The CardioWatch 287-2 System can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.<br><br>The CardioWatch 287-2 System is not intended for use in high-acuity environments, such as ICU or operating rooms.<br><br>The CardioWatch 287-2 System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The CardioWatch 287-2 system is not a substitute for an ECG monitor.<br><br>The CardioWatch 287-2 System is not intended for SpO2 monitoring in conditions of high motion or low perfusion | The CardioWatch 287-2 System is not intended for use in high-acuity environments, such as ICU or operating rooms.<br><br>The CardioWatch 287-2 System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The CardioWatch 287-2 system is not a substitute for an ECG monitor.<br><br>The CardioWatch 287-2 System is not intended for SpO2 monitoring in conditions of high motion or low perfusion. | | |
| Target Population | Adult (22yrs & older) | Adult (22yrs & older) | Not declared | Identical. |
| Patient target category | Non acutely ill patients | Non acutely ill patients | Not declared | Identical |
| Wearing location | Wrist | Wrist | Wrist | Identical |
| Duration of Use | Upto 24 hours per day | Upto 24 hours per day | Upto 24 hours per day | Identical |

| Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: CardioWatch 287-2 System | Reference Device: ActiGraph CentrePoint Insight Watch | Comment |
|---|---|---|---|---|
| | as required by the practician | as required by the practician | as required by the practician | |
| Sterile | Non-sterile | Non-sterile | Non-sterile | Identical |
| Mechanism of Action / Principle of Operation | The Corsano CardioWatch 287-2 System continuously monitors Pulse Rate (PR), oxygen saturation (SpO2), temperature (sTEMP), Sleep-Wake (SLEEP) and Activity (STEPS) and intermittently the respiration rate (RESP) through sensors in the wrist bracelet. | The Corsano CardioWatch 287-2 System continuously monitors Pulse Rate (PR), oxygen saturation (SpO2), temperature (sTEMP) and Activity (STEPS) and intermittently the respiration rate (RESP) through sensors in the wrist bracelet. | The watch acquires and stores data on an onboard accelerometer while being worn during normal activities and/or during sleep.<br>The data record is timestamped and stored in non-volatile memory for later retrieval.<br>Downloaded data can be post-processed based on the timestamp and magnitude of acceleration along each axis. | Identical to the Predicate Device, with the addition of Sleep-Wake assessment. |
| | The Corsano System monitors, skin temperature (sTEMP) at wrist or axillary temperature (aTEMP) with connected thermometer. | The Corsano System monitors skin temperature (sTEMP) at wrist or axillary temperature (aTEMP) with connected thermometer. | - | Identical, no change to Predicate Device. |
| | Microelectromechanical system<br>(MEMS)-based integrated circuit | Microelectromechanical system<br>(MEMS)-based integrated circuit | Core data collection sensor is a 3-axis microelectromechanical system (MEMS) accelerometer. | Identical |
| | The device has wireless communication capabilities. | The device has wireless communication capabilities. | USB to communicate with a PC or peripheral.<br>Bluetooth BLE. | Similar |
| | Intermittent or spot-checking monitoring of blood pressure (BP), spirometry & lung function (SPIRO) and weight (WEIGHT) through third-party product integration. | Intermittent or spot-checking monitoring of blood pressure (BP), spirometry & lung function (SPIRO) and weight (WEIGHT) through third-party product integration. | N/A | Identical. |

| Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: CardioWatch 287-2 System | Reference Device: ActiGraph CentrePoint Insight Watch | Comment |
|---|---|---|---|---|
| PPG Sensor Characteristics | | | | |
| Green LED | 525nm | 530nm | - | Identical to predicate device |
| Red LED | 660nm | 660nm | - | Identical to predicate device |
| IR LED | 880nm | 930nm | - | Identical to predicate device |
| Connected External Third-Party Devices | Non-invasive blood pressure monitor<br>Weight scale<br>Thermometer<br>Spirometer | Non-invasive blood pressure monitor<br>Weight scale<br>Thermometer<br>Spirometer | N/A | Identical to predicate device |
| Alarms overview | Visible and audible alerts for PR, SpO2, Respiration rate, Axillary Temperature, outside limits. | Visible and audible alerts for PR, SpO2, Respiration rate, Axillary Temperature outside limits. | No alarms | Identical to predicate device |
| User Interfaces | | | | |
| - HCP | Mobile device application, and cloud software platform | Mobile device application, and cloud software platform | N/A : no device HCP interface. | Identical to predicate device |
| - Patient | Mobile device application | Mobile device application | LCD screen on the device shows battery level, functional status, and time of day. | Identical to predicate device |
| Wearable Sensors | PPG,<br>Accelerometer,<br>Thermopile, | PPG,<br>Accelerometer,<br>Thermopile | -<br>Accelerometer,<br>Near-body temperature sensor. | Identical to predicate device |
| Energy Source | Battery | Battery | Battery | Same |
| Battery Type | Rechargeable Lithium-Ion | Rechargeable Lithium-Ion | Rechargeable Lithium-Ion | Identical. |
| Wireless Communication Means | Yes | Yes | Yes | Identical |
| OTC/Prescriptio | Prescription Use | Prescription Use | Prescription Use | Identical |

| Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: CardioWatch 287-2 System | Reference Device: ActiGraph CentrePoint Insight Watch | Comment |
|---|---|---|---|---|
| n Use | - | - | - | |
| Use Environment | Professional Healthcare Facilities and Home | Professional Healthcare Facilities and Home | Not declared in 510k nor current labelling. | Identical to predicate device |

Performance Features :

| Performance Features | Proposed Device: CardioWatch 287-2 System | Predicate Device: Current Wearable Health Monitoring System | Comment |
|---|---|---|---|
| Pulse Rate Measurement Range | 25 BPM to 250 BPM | 30 BPM to 240 BPM | Similar range; no impact safety & effectiveness as validation has been made through bench & clinical testing. |
| Pulse Rate Accuracy | 3 BPM ARMS | 3 BPM ARMS | Identical, both comply with ISO 80601-2-61. |
| SpO2 Measurement Range | 70% to 100% | 70% to 100% | Identical |
| Sp02 Measurement Resolution | 1% | 1% | Identical |
| SpO2 Accuracy | <2 % Arms for Range 70-100% | +/- 2 Digits | Identical, both comply with ISO 80601-2-61 as well as with FDA Guidance for Pulse Oximeters (2013). |
| RR Measurement Range | 4-60 RPM | 6-60 RPM | Similar range; no impact safety & effectiveness as validation has been made through bench & clinical testing. |
| RR Measurement Resolution | 1 brpm | 1 brpm | Identical |
| RR Accuracy | +/- 3 RPM ARMS | +/- 3 RPM | Identical |
| Skin Temperature Measurement Range | 34.0°C to 42.0°C (93.2°F to 107.6°F) | -20.0°C to 50.0°C (-4°F to 122°F) | Difference in range claims ; no impact on safety & effectiveness as validation has been made through bench testing in accordance with IEC80601-2-56. Value provided by predicated device corresponds to the thermistor specifications. |
| Skin Temperature Measurement Resolution | 0.1ºC | 0.1ºC | Identical |
| Skin Temperature Accuracy | +/- 0.3°C (0.54°F) | +/- 0.1°C (0.18°F) | Difference; no comparison is possible as the predicate device provides the performance of the thermistor sensor & not the wearable device. |

# 5 PERFORMANCE TESTING

Corsano CardioWatch 287-2 System has been designed and developed according to a robust hardware & software development process and was rigorously verified and validated and complies with the following standards/guidance through testing and/or analysis:

Recognised standards :

- IEC 60601-1:2005/A2:2020
- IEC 60601-1-2:2014/A1:2020
- IEC 60601-1-8:2006, AMD1:2012, AMD2:2020 :
- IEC 60601-1-11:2015/A1:2020
- ISO 80601-2-56:2017/AMD11:2018
- ISO 80601-2-61:2018
- IEC 81001-5-1:2022
- ISO 14971:2019 + A11:2021
- IEC 62304:2006+AMD1:2015
- IEC 62366-1:2015 + AC:2015 + A1:2020
- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-10:2010
- ISO 10993-10:2021
- ISO 20417:2021
- ISO 15223-1:2021
- ASTM D4169-16

FDA Guidance :

- Pulse Oximeters - Premarket Notification Submissions [510(k)s] ; March 4, 2013
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" ; Sept 8, 2023
- Applying Human Factors and Usability Engineering to Medical Devices; Feb 3, 2016
- Content of Premarket Submissions for Device Software Functions; June 14, 2023
- Policy for Device Software Functions and Mobile Medical Applications; Sept 28, 2022
- Multiple Function Device Products: Policy and Considerations, July 29, 2020
- Off-The-Shelf Software Use in Medical Devices, August 11, 2023
- General principles of software validation ; January 11, 2002.
- Postmarket Management of Cybersecurity in Medical Devices; Dec 28, 2016
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions ; Feb 3, 2026

- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices; September 6, 2017
- Electromagnetic Compatibility (EMC) of Medical Devices; June 6, 2022
- Radio Frequency Wireless Technology in Medical Devices; Aug 14, 2013
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; March 17, 2015

Animal Studies
No animal studies were conducted as part of submission to prove substantial equivalence.

Clinical Studies
A clinical trial was conducted as part of the submission demonstrating that the CardioWatch 287-2's Sleep/Wake classification is accurate compared to the reference gold standard PSG, with an overall accuracy of 97.0%, a sensitivity of 98.3% and a specificity of 83.7%. These results are similar across different genders, BMI's and Fitzpatrick scales

The CardioWatch 287-2 shows accurate results in determining the Sleep Onset, Rise Time, TST, Awakening, WASO and Efficiency compared to the reference gold standard PSG. Both for the pooled data but also for different genders, BMI's and Fitzpatrick Scales.

# 6 Conclusion

Based on the information presented in this substantial equivalence comparison, the Corsano CardioWatch 287-2 System can be considered substantially equivalent to the previously cleared Corsano CardioWatch 287-2 System (K232548) and that of the Reference Device (K181077) in terms of safety, performance, functionality and indications for use and can thus be considered as safe and as effective.