Summary Safety & Effectiveness

1 GENERAL INFORMATION

Submitter and 510(k) Owner	
Name	Corsano Health B.V.
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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. 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. 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. The device is intended to monitor the activity associated with movement during sleep. 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. 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 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 • Temperature • Movement 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		

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. 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	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.		
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. The data record is timestamped and stored in non-volatile memory for later retrieval. 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 (MEMS)-based integrated circuit	Microelectromechanical system (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. 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 Weight scale Thermometer Spirometer	Non-invasive blood pressure monitor Weight scale Thermometer 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, Accelerometer, Thermopile,	PPG, Accelerometer, Thermopile	- Accelerometer, 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.