March 22, 2024

Corsano Health B.V.
Peter Stas
CEO - Head of Firm
Wilhelmina van Pruisenweg 35
2595AN ‘s-Gravenhage
The Netherlands

Re: K232548
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
Dated: February 16, 2024
Received: February 20, 2024

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 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,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K232548

Device Name
Corsano CardioWatch 287-2 System

Indications for Use *(Describe)*
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
• 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

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.

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

1 GENERAL INFORMATION

Submitter and 510(k) Owner	
Name	Corsano Health B.V.
Address :	Wilhelmina Van Pruisenweg 35 's-Gravenhage 2595 AN Netherlands
Official Correspondent	Mr Peter STAS, CEO – Head of firm
Phone	+41793102442
Email :	pcstas@corsano.com
Date of Summary :	22nd March 2024

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

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

Secondary Product Codes				
Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
21 CFR 870.2910	Clinical Electronic Thermometer	Class II	FLL	General Hospital
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

Predicate Device	
Trade/Proprietary Name	Current Wearable Health Monitoring System
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

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 (STEPS) 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 trained healthcare professionals.

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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
• 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

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.

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4 Substantial Equivalence

The Corsano CardioWatch 287-2 System has an intended use statement identical to the predicate device with the exception of several word changes specific to the CardioWatch 287-2 System, both the devices also share same conditions of use in terms measurement technology, measurements, transmission, data visualization and alarms whilst using third party devices, 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 predicate device, providing patient physiological parameters measurements using PPG technology on wearable sensors, transmit and provide data visualization and alarms (visual & audible) to HCP's.

Both systems provide the possibility of using validated third-party devices that provide additional physiological parameters & data visualization to HCP's.

Features	Proposed Device: CardioWatch 287-2 System	Predicate Device: Current Wearable Health Monitoring System	Comment
Device Manufacturer	Corsano Health B.V.	Current Health Ltd	-
Device Classification	II	II	Identical
510(k) Number	N/A	K210133	-
Primary Product Code	MSX	MSX	Identical
Secondary Product Code	DQA	DQA	Identical
	BZQ	BZQ	Identical
	FLL	FLL	Identical (Clinical Electronic Thermometer) both for wearable sensor & third-party device
	DRG	DRG	Identical (Radiofrequency physiological signal transmitter & receiver)
	BZG	BZG	Identical (Spirometer - third-party device)
	DXN	-	Both devices use the NIPB (third-party device), however the Predicate device has not included the Product Code.

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Features	Proposed Device: CardioWatch 287-2 System	Predicate Device: Current Wearable Health Monitoring System	Comment
	FRI	-	Both devices use the Scales (third-party device), however the Predicate device has not included the Product Code.
Device Classification Name	System, Network and Communication, Physiological Monitors	System, Network and Communication, Physiological Monitors	Identical
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 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 Current Wearable Health Monitoring 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 patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults: • Pulse rate • Oxygen saturation • Temperature • Movement	Identical both devices can be considered similar in terms of intended use (measurements, transmission, data visualization, alarms and third party devices) in the same healthcare environments and the same intended patients.

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Features	Proposed Device: CardioWatch 287-2 System	Predicate Device: Current Wearable Health Monitoring System	Comment
	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 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 Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of: • Respiration rate • Non-invasive blood pressure • Lung function & spirometry • Weight The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms. The Current Wearable Health Monitoring 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 Current Wearable Health Monitoring System is not a substitute for an ECG monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.	

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Features	Proposed Device: CardioWatch 287-2 System	Predicate Device: Current Wearable Health Monitoring System	Comment
Target Population	Adult (22yrs & older)	Adult (18yrs & older)	Similar ; both devices are intended for use on adults
Patient target category	Non acutely ill patients	Non acutely ill patients	Identical
Wearing location	Wrist	Upper arm	The difference in wearing location on the body does not raise new questions of safety or efficacy. Both locations are valid clinical locations allowing for monitoring peripheral arteries.
Duration of Use	Upto 24 hours per day as required by the practician	Upto 24 hours per day as required by the practician	Identical
Sterile	Non-sterile	No-sterile	Identical
Mechanism of Action / Principle of Operation	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 Current Health System continuously monitors pulse rate (PR), oxygen saturation (SpO2), skin temperature (TEMP) and movement (MOVEMENT) through sensors in a device designed to be worn around the upper arm.	Identical, both devices use their own wearable sensor to provide these measurements.
	The Corsano System monitors skin temperature (sTEMP) at wrist or axillary temperature (aTEMP) with connected thermometer.	The Current Health System monitors skin temperature (sTEMP) at upper arm or axillary temperature (aTEMP) with connected thermometer.	Identical, both devices use their own wearable sensor, in addition to providing measurement using with FDA cleared third-Party External device.
	The device has wireless communication capabilities.	The device has wireless communication capabilities.	Identical
	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 respiration rate (RESP), blood pressure (BP), spirometry & lung function (SPIRO), and weight (WEIGHT) through third-party product integration.	Identical
PPG Sensor Characteristics			
Green LED	525nm	530nm	Similar wavelength, in that the non-significant difference of 5nm has no impact on the safety, and the effectiveness has been demonstrated in the Bench &

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Features	Proposed Device: CardioWatch 287-2 System	Predicate Device: Current Wearable Health Monitoring System	Comment
			Clinical Testing.
Red LED	660nm	660nm	Identical wavelength
IR LED	880nm	930nm	Similar wavelength, in that the non-significant difference of 50nm has no impact on the safety, and the effectiveness has been demonstrated in the Bench & Clinical Testing.
Connected External Third-Party Devices	Non-invasive blood pressure monitor Weight scale Thermometer Spirometer	Non-invasive blood pressure monitor Weight scale Thermometer Spirometer	Identical
Alarms overview	Visible and audible alerts for PR, SpO2, Axillary Temperature outside limits.	Visible and audible alerts for PR, SpO2, Temperature outside limits.	Identical
User Interfaces			
HCP	Mobile device application, and cloud software platform	Mobile device and central station	Identical
Patient	Mobile device application	Mobile device application	Identical
Wearable Sensors	PPG, Accelerometer, Thermopile	PPG, Accelerometer, Thermopile	Identical
Energy Source	Battery	Battery	Identical
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	Identical
Wireless Communication Means	Yes	Yes	Identical
OTC/Prescription Use	Prescription Use	Prescription Use	Identical
Environment	Professional Healthcare Facilities and Home	Professional Healthcare Facilities and Home	Identical

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.

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Performance Features	Proposed Device: CardioWatch 287-2 System	Predicate Device: Current Wearable Health Monitoring System	Comment
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.

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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
- 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 4, 2020
- 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
- Off-the-shelf software use in medical devices, 27 Sep 2019.
- General principles of software validation ; January 11, 2002.
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Oct 2, 2014
- Postmarket Management of Cybersecurity in Medical Devices; Dec 28, 2016

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- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Draft Guidance) ; April 8, 2022
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software; Jan 2005
- 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
No clinical studies were conducted as part of the submission to prove substantial equivalence.

Clinical studies were carried out to support compliance to IEC IEC 80601-2-61 and FDA Guidance on Pulse Oximeters - Premarket Notification Submissions [510(k)s], March 2013. The Respiratory Rate Validation Testing ensured RR accuracy of the Corsano CardioWatch 287-2 System in the intended patient population using the gold standard (blinded clinician, manually counted end-tidal CO2 with FDA cleared capnogram).

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 already cleared Current Wearable Health Monitoring in terms of safety, performance, functionality and indications for use and can thus be considered as safe and as effective as the cleared Predicate Device (K210133).