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) ☐ 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) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?