

K172510 μ Cor Heart Failure and Arrhythmia Management System

May 11, 2018
263 days to decisionK172510 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k172510/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 21, 2017
Decision date	May 11, 2018
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zoll Manufacturing Corporation
Location	Pittsburgh,, PA, US
Contact	Dawn Chang
510(k) history	3 submissions · 3 cleared · 2018-2019

CLINICAL EVIDENCE - NCT02975050

Vital Signs Validation Study of the μ -Cor System (ViVUS Validation)

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	30 patients (actual)
Condition studied	Health Volunteer Validation Study
Study type	Observational
Completion date	Jan 19, 2017
Sponsor	Zoll Medical Corporation (Industry)

Primary outcome

Respiratory rate

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02975050510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172510/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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