FDA 510(k) Premarket Notification

CLEARED

K190939 ZOLL Arrhythmia Management Sysyem

Dec 19, 2019
253 days to decision

K190939 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k190939/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 10, 2019
Decision date	Dec 19, 2019
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Nilo Medical Consulting Group**
Contact	Michael Nilo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov