FDA 510(k) Premarket Notification

CLEARED

K220117 ARC Intensive Care Information System (ARC System)

Jun 6, 2023
508 days to decision

K220117 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k220117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jan 14, 2022
Decision date	Jun 6, 2023
Days to decision	508 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ordinatrum Solutions**
Location	Tustin, CA, US
Contact	Ali Yasin Ozturk
510(k) history	1 submissions · 1 cleared · 2023-2023

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