FDA 510(k) Premarket Notification

K230214 Huma RPM (RPM)

CLEARED

Jun 2, 2023
127 days to decision

K230214 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k230214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jan 26, 2023
Decision date	Jun 2, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medopad, Inc.**
Location	New York, NY, US
Contact	Mani Shanmugham
510(k) history	1 submissions · 1 cleared · 2023-2023