FDA 510(k) Premarket Notification

K212975 MedWand

CLEARED

Jul 22, 2022
308 days to decision

K212975 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k212975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 17, 2021
Decision date	Jul 22, 2022
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medwand Solutions, Inc.**
Location	Rancho Santa Margarita, CA, US
Contact	Robert Rose
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**NJK & Associates, Inc.**
Contact	Natalie J Kennel

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