FDA 510(k) Premarket Notification

K212622 Zyter RPM

CLEARED

Feb 11, 2022
177 days to decision

K212622 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k212622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Aug 18, 2021
Decision date	Feb 11, 2022
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zyter, Inc.**
Location	Rockville, MD, US
Contact	Lakshmi Narayana Babu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Mary Vater

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