FDA 510(k) Premarket Notification

K200160 740 SafeSAT

CLEARED

Feb 15, 2021
390 days to decision

K200160 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k200160/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jan 22, 2020
Decision date	Feb 15, 2021
Days to decision	390 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zoe Medical, Inc.**
Location	Topsfield, MA, US
Contact	Jim Chickering
510(k) history	5 submissions · 5 cleared · 2001-2021