

K200160 740 SafeSATFeb 15, 2021
390 days to decisionK200160 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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