

K231477 Infinity CentralStation Wide, Infinity M300, Infinity M300+

Oct 17, 2023
148 days to decision

K231477 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k231477/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 22, 2023
Decision date	Oct 17, 2023
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Draeger Medical Systems, Inc.
Location	Danvers, MA, US
Contact	Deborah Herrington
510(k) history	48 submissions · 48 cleared · 2003-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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