

K240312 Infinity CentralStation WideAug 1, 2024
181 days to decisionK240312 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k240312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 2, 2024
Decision date	Aug 1, 2024
Days to decision	181 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	Patrice Cocco
510(k) history	48 submissions · 48 cleared · 2003-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026