

K200859 Infinity M300Aug 28, 2020
149 days to decisionK200859 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k200859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 1, 2020
Decision date	Aug 28, 2020
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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