

**K203088 Infinity Acute Care System (IACS) Monitoring System**Feb 1, 2022  
476 days to decisionK203088 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k203088/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 13, 2020
Decision date	Feb 1, 2022
Days to decision	476 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203088/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026