

**K201764 Infinity Acute Care System (IACS) Monitoring Solution**Dec 9, 2021  
528 days to decisionK201764 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201764/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 29, 2020
Decision date	Dec 9, 2021
Days to decision	528 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201764/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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