

**K113798 INFINITY ACUTE CARE SYSTEM, INFINITY MCABLE-MASIMO RAINBOW SET**Mar 22, 2012  
90 days to decisionK113798 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113798/>**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	Dec 23, 2011
Decision date	Mar 22, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Draeger Medical Systems, Inc.</b>
Location	Danvers, MA, US
Contact	BETH A ZIS
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/k113798/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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