

**K051628 INFINITY MONITORS WITH SCIO MODIFICATIONS**Jul 20, 2005  
30 days to decisionK051628 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k051628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 20, 2005
Decision date	Jul 20, 2005
Days to decision	30 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	PENELOPE H GRECO
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/k051628/> 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 24, 2026