

**K041087 INFINITY GAMMA**May 12, 2004  
16 days to decisionK041087 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k041087/>**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	Apr 26, 2004
Decision date	May 12, 2004
Days to decision	16 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/k041087/> 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