

**K070566 INFINITY DELTA/DELTA XL/ KAPPA/ GAMMA X XL/
VISTA XL/ SC7000/SC8000/ SC9000XL**

Jun 4, 2007
96 days to decision

K070566 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k070566/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 28, 2007
Decision date	Jun 4, 2007
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Draeger Medical Systems, Inc.
Location	Danvers, MA, US
Contact	MARK KIERAS
510(k) history	48 submissions · 48 cleared · 2003-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k070566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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