

**K043439 INFINITY MODULAR MONITORS WITH VF5
MODIFICATIONS (DELTA/KAPPA/DELTA XL/VISTA XL/GAMMA
X XL AND SC 7000/8000/9000XL**Feb 18, 2005
66 days to decisionK043439 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k043439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 14, 2004
Decision date	Feb 18, 2005
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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