

**K033957 INFINITY MODULAR MONITORS VF4 MODIFICATIONS  
WITH SCIO, MODELS DELTA, DELTA XL, KAPPA, SC 8000, SC  
7000, SC 9000XL**May 14, 2004  
144 days to decisionK033957 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k033957/>**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	Dec 22, 2003
Decision date	May 14, 2004
Days to decision	144 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/k033957/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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