

K042904 INFINITY KAPPA XLTFeb 18, 2005
120 days to decisionK042904 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k042904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 21, 2004
Decision date	Feb 18, 2005
Days to decision	120 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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