

K152407 Infinity Delta, Infinity Delta XL, Infinity KappaSep 23, 2015
29 days to decisionK152407 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k152407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 25, 2015
Decision date	Sep 23, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Draeger Medical Sytems, Inc.
Location	Andover, MA, US
Contact	Beth Zis
510(k) history	2 submissions · 2 cleared · 2015-2018

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