

K113054 EQUIVITALFeb 17, 2012
127 days to decisionK113054 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k113054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 13, 2011
Decision date	Feb 17, 2012
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hidalgo Limited
Location	Swavesey Cambridge, GB
Contact	EKTA SOOD
510(k) history	2 submissions · 2 cleared · 2006-2012

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