

K133576 MONITOR B40Feb 21, 2014
93 days to decisionK133576 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k133576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 20, 2013
Decision date	Feb 21, 2014
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems China Co., Ltd.
Location	Wuxi, Jiangsu Province, CN
Contact	ROBERT CASARSA
510(k) history	13 submissions · 13 cleared · 2009-2017

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