

**K130584 MONITOR B40**Jun 26, 2013  
113 days to decisionK130584 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Mar 5, 2013
Decision date	Jun 26, 2013
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130584/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026