

**K171580 Monitor B125, Monitor B105**Nov 1, 2017  
154 days to decisionK171580 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k171580/>**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	May 31, 2017
Decision date	Nov 1, 2017
Days to decision	154 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	Sun YanLi
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/k171580/> 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