

K151063 Monitor B40Dec 15, 2015
239 days to decisionK151063 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k151063/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received | Apr 20, 2015 |
| Decision date | Dec 15, 2015 |
| Days to decision | 239 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151063/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026