

K143676 B40i Patient MonitorJul 31, 2015
219 days to decisionK143676 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k143676/>**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 | Dec 24, 2014 |
| Decision date | Jul 31, 2015 |
| Days to decision | 219 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | GE Healthcare Finland Oy |
| Location | Madison, WI, US |
| Contact | JOEL KENT |
| 510(k) history | 30 submissions · 30 cleared · 2007-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143676/> 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 24, 2026