

**K131414 CARESCAPE MONITOR B850**Aug 28, 2013  
104 days to decisionK131414 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k131414/>**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 16, 2013   |
| Decision date         | Aug 28, 2013   |
| Days to decision      | 104 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131414/> 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 24, 2026