

**K153707 Nihon Kohden Vital Sign Telemeter**Sep 2, 2016  
254 days to decisionK153707 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153707/>**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 23, 2015   |
| Decision date         | Sep 2, 2016  |
| Days to decision      | 254 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nihon Kohden Corporation</b>         |
| Location       | Tokyo, JP                               |
| Contact        | TOM BENTO                               |
| 510(k) history | 18 submissions · 18 cleared · 2015-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153707/> 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