

K001433 CNS-9300 SERIES CENTRAL STATIONNov 7, 2000
183 days to decisionK001433 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k001433/>**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 8, 2000 |
| Decision date | Nov 7, 2000 |
| Days to decision | 183 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nihon Kohden America, Inc. |
| Location | Foothill Ranch, CA, US |
| Contact | BONNIE BISHOP |
| 510(k) history | 166 submissions · 163 cleared · 1979-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001433/> 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