

**K862463 LIFESCOPE 8, OEC-8120 PORTABLE PATIENT
MONITOR REC**Dec 5, 1986
158 days to decisionK862463 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k862463/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received | Jun 30, 1986 |
| Decision date | Dec 5, 1986 |
| Days to decision | 158 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862463/> 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