

**K850897 FUKUDA DENSHI DS-1020A & DS-1040A DYNASCOPIY  
SERIES**Apr 10, 1985  
37 days to decisionK850897 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k850897/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received         | Mar 4, 1985                          |
| Decision date         | Apr 10, 1985                         |
| Days to decision      | 37 days                              |
| Third-party review    | No                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Fukuda Denshi USA, Inc.</b>          |
| Location       | Mchenry, IL, US                         |
| Contact        | DON ANDRESEN                            |
| 510(k) history | 68 submissions · 68 cleared · 1984-2018 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850897/>; 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 18, 2026