

**K852469 SAF-D-FIB**Sep 16, 1985  
95 days to decisionK852469 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k852469/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jun 13, 1985
Decision date	Sep 16, 1985
Days to decision	95 days
Third-party review	No

**APPLICANT**

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Company	<b>Medtronic Andover Medical, Inc.</b>
Location	Lowell, MA, US
Contact	EDWARD SHAUGHNESSY
510(k) history	6 submissions · 6 cleared · 1985-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852469/>; 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 14, 2026