

**K855045 MODEL 535 NEO-TRAK RECORDER**May 16, 1986  
150 days to decisionK855045 · Product code: **DSF** · CardiovascularSource: <https://www.510kdatabase.net/k855045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Paper Chart (DSF)
Date received	Dec 17, 1985
Decision date	May 16, 1986
Days to decision	150 days
Third-party review	No

**APPLICANT**

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Company	<b>Ge Medical Systems Information Technologies</b>
Location	Mchenry, IL, US
Contact	JOSEPH P LENZEN
510(k) history	136 submissions · 132 cleared · 1978-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k855045/>; 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 26, 2026