

**K828543 UNKNOWN**Jan 1, 1985  
775 days to decisionK828543 · Radiology  
Source: <https://www.510kdatabase.net/k828543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Nov 18, 1982
Decision date	Jan 1, 1985
Days to decision	775 days
Third-party review	No

**APPLICANT**

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Company	<b>General Electric Co.</b>
Location	Mchenry, IL, US
510(k) history	254 submissions · 254 cleared · 1976-2011

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k828543/> 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 17, 2026