

**K845048 NEPHROSTOMY DRAINAGE CATHETER & STIFFENER**Jan 15, 1985  
15 days to decisionK845048 · Product code: **LJE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k845048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Dec 31, 1984
Decision date	Jan 15, 1985
Days to decision	15 days
Third-party review	No

**APPLICANT**

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Company	<b>American Edwards Laboratories</b>
Location	Walker, MI, US
Contact	RONALD J EHMTEN
510(k) history	89 submissions · 88 cleared · 1980-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k845048/>; 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