

**K864330 SHEAR FORCE GAUGE**Jan 6, 1987  
63 days to decisionK864330 · Product code: **DXE** · CardiovascularSource: <https://www.510kdatabase.net/k864330/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Nov 4, 1986
Decision date	Jan 6, 1987
Days to decision	63 days
Third-party review	No

**APPLICANT**

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Company	<b>American Edwards Laboratories</b>
Location	Walker, MI, US
Contact	MARK COLE
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/k864330/>, 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