

**K811399 EDSLAB CLOSED INJECTATE DELIVERY SYSTEM**Jun 9, 1981  
21 days to decisionK811399 · Product code: **KRB** · CardiovascularSource: <https://www.510kdatabase.net/k811399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Thermodilution (KRB)
Date received	May 19, 1981
Decision date	Jun 9, 1981
Days to decision	21 days
Third-party review	No

**APPLICANT**

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Company	<b>American Edwards Laboratories</b>
Location	Walker, MI, US
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/k811399/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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