

**K870804 CARDIOPLEGIA HEAT EXCHANGER MODEL NO.  
HE-100**Sep 1, 1987  
186 days to decisionK870804 · Product code: **DTR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k870804/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Feb 27, 1987
Decision date	Sep 1, 1987
Days to decision	186 days
Third-party review	No

**APPLICANT**

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Company	<b>American Bentley</b>
Location	Mchenry, IL, US
Contact	DONALD A RAIBLE
510(k) history	59 submissions · 59 cleared · 1983-1988

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k870804/>; 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 27, 2026