

**K883330 BASIC HEATER-COOLER UNIT, 115/100V 16-02-20**Sep 26, 1988  
49 days to decisionK883330 · Product code: **DTR** · CardiovascularSource: <https://www.510kdatabase.net/k883330/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Aug 8, 1988
Decision date	Sep 26, 1988
Days to decision	49 days
Third-party review	No

**APPLICANT**

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Company	<b>Shiley, Inc.</b>
Location	Mchenry, IL, US
Contact	GANZ POBUDA
510(k) history	174 submissions · 174 cleared · 1976-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883330/>, 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 26, 2026