

**K883331 BASIC HEATER-COOLER UNIT W/MAST, 115/110V  
16-21-10**Sep 26, 1988  
49 days to decisionK883331 · Product code: **DTR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k883331/>**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/k883331/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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