

**K893940 POLYSTAN HEATER-COOLER UNIT**Jan 18, 1990  
232 days to decisionK893940 · Product code: **DWC** · CardiovascularSource: <https://www.510kdatabase.net/k893940/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	May 31, 1989
Decision date	Jan 18, 1990
Days to decision	232 days
Third-party review	No

**APPLICANT**

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Company	<b>Polystan C/O Vitalcor, Inc.</b>
Location	Ballerup Denmark, US
Contact	HENNING S LARSEN
510(k) history	8 submissions · 8 cleared · 1984-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k893940/>, 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 June 29, 2026