

**K892641 BARD WM HARVEY HF-5700 MEMB OXYGEN  
W/HARDSHELL RES**Nov 1, 1989  
203 days to decisionK892641 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k892641/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 12, 1989
Decision date	Nov 1, 1989
Days to decision	203 days
Third-party review	No

**APPLICANT**

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Company	<b>Bard Cardiosurgery Div</b>
Location	Billerica, MA, US
Contact	CHRISTINE MORGIDA
510(k) history	3 submissions · 3 cleared · 1989-1992

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892641/>; 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