

**K892664 CARDIOPULMONARY SUPPORT (CPS) SYSTEM**Feb 13, 1990  
306 days to decisionK892664 · Product code: **DTZ** · CardiovascularSource: <https://www.510kdatabase.net/k892664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 13, 1989
Decision date	Feb 13, 1990
Days to decision	306 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/k892664/>; 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