

**K945720 JOSTRA HL-15 MODULAR HEART-LUNG MACHINE  
(HEREINAFTER CALLED THE HL-15 OR THE DEVICE)**Mar 29, 1995  
128 days to decisionK945720 · Product code: **DWC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k945720/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Nov 21, 1994
Decision date	Mar 29, 1995
Days to decision	128 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Jostra Bentley</b>
Location	Austin, TX, US
Contact	RICHARD MARTIN
510(k) history	3 submissions · 3 cleared · 1995-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945720/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026