

**K964673 BAIR HUGGER MODEL 630 CARDIAC BLANKET**Jun 26, 1997  
217 days to decisionK964673 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k964673/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Nov 21, 1996
Decision date	Jun 26, 1997
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Augustine Medical, Inc.</b>
Location	Eden Prairie, MN, US
Contact	SCOTT D AUGUSTINE
510(k) history	25 submissions · 24 cleared · 1987-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964673/> 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 May 26, 2026