

**K161602 Arctic Sun Temperature Management System**Sep 2, 2016  
85 days to decisionK161602 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k161602/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Thermal Regulating (DWJ)
Date received	Jun 9, 2016
Decision date	Sep 2, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medivance, Inc.</b>
Location	Louisville, CO, US
Contact	Stacci Cronk
510(k) history	12 submissions · 12 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161602/> 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 25, 2026