

K101092 ARCTIC SUN TEMPERATURE MANAGEMENT SYSTEM, MODEL 5000Jul 16, 2010
87 days to decisionK101092 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k101092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Apr 20, 2010
Decision date	Jul 16, 2010
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medivance, Inc.
Location	Louisville, CO, US
Contact	LYNNE ARONSON
510(k) history	12 submissions · 12 cleared · 2000-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101092/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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