

K243942 Arctic Sun Stat Temperature Management SystemApr 30, 2025
131 days to decisionK243942 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k243942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Dec 20, 2024
Decision date	Apr 30, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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