

K200225 Arctic Sun Stat Temperature Management SystemFeb 28, 2020
29 days to decisionK200225 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k200225/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Thermal Regulating (DWJ) |
| Date received | Jan 30, 2020 |
| Decision date | Feb 28, 2020 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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