

**K120081 NORM-O-TEMP HYPERTHERMIA SYSTEM INCLUDING
BLANKETS/PADS**Feb 17, 2012
37 days to decisionK120081 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k120081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jan 11, 2012
Decision date	Feb 17, 2012
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cincinnati Sub-Zero Products, Inc.
Location	Sharonville, OH, US
Contact	STEVEN J BERKE
510(k) history	12 submissions · 12 cleared · 1991-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120081/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026