

**K110104 BLANKETROL II HYPER-HYPOTHERMIA  
TEMPERATURE MANAGMENT SYSTEM**Feb 4, 2011  
22 days to decisionK110104 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k110104/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jan 13, 2011
Decision date	Feb 4, 2011
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110104/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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