

**K101589 BLANKETROL III, MODEL 233 AND COOLBLUE,
MODEL 25-01 HYPER-HYPOTHERMIA SYSTEMS**

Sep 20, 2010
105 days to decision

K101589 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k101589/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jun 7, 2010
Decision date	Sep 20, 2010
Days to decision	105 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.net

Device record: <https://www.510kdatabase.net/k101589/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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