

K122813 HEMOTHERM MODEL 400CE COOLER/HEATER SYSTEMDec 18, 2012
96 days to decisionK122813 · Product code: **DWC** · Cardiovascular
Source: <https://www.510kdatabase.net/k122813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Sep 13, 2012
Decision date	Dec 18, 2012
Days to decision	96 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

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