

**K063829 THERMOGARD THERMAL REGULATION SYSTEM**Jan 22, 2007  
27 days to decisionK063829 · Product code: **NCX** · Neurology  
Source: <https://www.510kdatabase.net/k063829/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Dec 26, 2006
Decision date	Jan 22, 2007
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alsius Corp.</b>
Location	Irvine, CA, US
Contact	KENNETH A COLLINS
510(k) history	9 submissions · 5 cleared · 2003-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063829/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 24, 2026