

**K014241 COOLGARD 3000, COOLINE, START-UP, MODELS
3000, CL-2085B, CL-2295A, CG-500D**Aug 1, 2003
583 days to decisionK014241 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k014241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Dec 26, 2001
Decision date	Aug 1, 2003
Days to decision	583 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alsius Corp.
Location	Irvine, CA, US
Contact	KEN COLLINS
510(k) history	9 submissions · 5 cleared · 2003-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k014241/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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