

K030421 ALSIUS COOLGARD 3000 & ALSIUS CATHETER SYSTEMOct 23, 2003
255 days to decisionK030421 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k030421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Feb 10, 2003
Decision date	Oct 23, 2003
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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