

K060308 COOLGARD 3000Apr 26, 2006
78 days to decisionK060308 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k060308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Feb 7, 2006
Decision date	Apr 26, 2006
Days to decision	78 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/k060308/> Data sourced from FDA 510(k) public records (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. - Generated June 24, 2026