

K051912 COOL LINE CATHETER KIT, MODELS CL-2085B, CL-2295A

Oct 11, 2005
89 days to decision

K051912 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k051912/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Jul 14, 2005
Decision date	Oct 11, 2005
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary
Other names	ICY CATHETER KIT, MODEL IC-3585A; FORTIUS CATHETER KIT, MOD. FR-5093B

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.net

Device record: <https://www.510kdatabase.net/k051912/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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