

K150046 Start-Up Kit (SUK), Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange CatheterOct 30, 2015
291 days to decisionK150046 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k150046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Jan 12, 2015
Decision date	Oct 30, 2015
Days to decision	291 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zoll Circulation, Inc.
Location	San Jose, CA, US
Contact	Sam Nanavati
510(k) history	8 submissions · 3 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150046/> 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 May 25, 2026