

K220008 Solex 7 Intravascular Heat Exchange Catheter, Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange Catheter, Thermogard HQ Start-Up Kit, Thermogard HQ Start-Up Kit EX, Thermogard HQ Console

Jun 2, 2022
149 days to decision

K220008 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k220008/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Jan 4, 2022
Decision date	Jun 2, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220008/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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