

K223746 Solex 7 Intravascular Heat Exchange Catheter, Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange Catheter, Thermogard XP Console, Thermogard HQ ConsoleJan 13, 2023
30 days to decisionK223746 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k223746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Dec 14, 2022
Decision date	Jan 13, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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