

K213031 Solex 7 Intravascular Heat Exchange Catheter, Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange Catheter, Start-Up Kit, Coolgard 3000 Console, Thermogard XP ConsoleDec 20, 2021
90 days to decisionK213031 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k213031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Sep 21, 2021
Decision date	Dec 20, 2021
Days to decision	90 days
Third-party review	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

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