

**K153226 Solex 7 Intravascular Heat Exchange Catheter, ZOLL
Start-Up Kit**Mar 24, 2016
139 days to decisionK153226 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k153226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Nov 6, 2015
Decision date	Mar 24, 2016
Days to decision	139 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/k153226/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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