

K152946 TEMPEDYSep 15, 2016
345 days to decisionK152946 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k152946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Oct 6, 2015
Decision date	Sep 15, 2016
Days to decision	345 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seiratherm GmbH
Location	91074 Herzogenaurach, DE
Contact	MATTHIAS ROTH
510(k) history	1 submissions · 1 cleared · 2016-2016

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