

**K012512 SETPOINT ENDOVASCULAR TEMPERATURE
MANAGEMENT SYSTEM**Jun 11, 2002
309 days to decisionK012512 · Product code: **NCX** · Neurology
Source: <https://www.510kdatabase.net/k012512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hypothermia, Intravenous, Cooling (NCX)
Date received	Aug 6, 2001
Decision date	Jun 11, 2002
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiant Medical
Location	Redwood City, CA, US
Contact	ANDREW CLEELAND
510(k) history	6 submissions · 5 cleared · 2002-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012512/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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