

K143570 WIRIONJun 4, 2015
169 days to decisionK143570 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k143570/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Dec 17, 2014
Decision date	Jun 4, 2015
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gardia Medical
Location	Caesarea, IL
Contact	OHAD HAAS
510(k) history	1 submissions · 1 cleared · 2015-2015

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