

K180023 WIRIONMar 21, 2018
77 days to decisionK180023 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k180023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Jan 3, 2018
Decision date	Mar 21, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gardia Medical , Ltd.
Location	Caesarea, IL
Contact	Vardit Segal
510(k) history	1 submissions · 1 cleared · 2018-2018

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