

K181060 Solitaire 2 and Solitaire Platinum Revascularization Device

Aug 24, 2018
123 days to decision

K181060 · Product code: **POL** · Neurology
Source: <https://www.510kdatabase.net/k181060/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	Apr 23, 2018
Decision date	Aug 24, 2018
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Neurovascular
Location	Lrvine, CA, US
Contact	Amnon Talmor
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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