FDA 510(k) Premarket Notification

K191710 FlowTriever Retrieval/Aspiration System

CLEARED

Sep 5, 2019
71 days to decision

K191710 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k191710/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Jun 26, 2019
Decision date	Sep 5, 2019
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inari Medical**
Location	Irvine, CA, US
Contact	Eben Gordon
510(k) history	26 submissions · 26 cleared · 2015-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k191710/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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