FDA 510(k) Premarket Notification

CLEARED

K182233 FlowTriever Retrieval/Aspiration System

Oct 15, 2018
59 days to decision

K182233 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k182233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Aug 17, 2018
Decision date	Oct 15, 2018
Days to decision	59 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