FDA 510(k) Premarket Notification

K230912 Artix BG

CLEARED

May 2, 2023
32 days to decision

K230912 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k230912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Mar 31, 2023
Decision date	May 2, 2023
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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