FDA 510(k) Premarket Notification

K221846 Artix Ballon Guiding Sheath

CLEARED

Jul 11, 2022
17 days to decision

K221846 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k221846/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 24, 2022
Decision date	Jul 11, 2022
Days to decision	17 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov