

K221846 Artix Ballon Guiding SheathJul 11, 2022
17 days to decisionK221846 · Product code: **DQY** · CardiovascularSource: <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	Ellen 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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221846/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026