FDA 510(k) Premarket Notification

K212392 Intri24 Sheath

CLEARED

Apr 1, 2022
242 days to decision

K212392 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k212392/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 2, 2021
Decision date	Apr 1, 2022
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inari Medical, Inc.**
Location	Aliso Viejo, CA, US
Contact	Kit Cariquitan
510(k) history	30 submissions · 30 cleared · 2015-2025