

K231108 Talon Transseptal SheathSep 27, 2023
161 days to decisionK231108 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k231108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 19, 2023
Decision date	Sep 27, 2023
Days to decision	161 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	Ellen Nguyen
510(k) history	30 submissions · 30 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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