FDA 510(k) Premarket Notification

K252027 Vertex(TM) Catheter

CLEARED

Sep 12, 2025
74 days to decision

K252027 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k252027/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 30, 2025
Decision date	Sep 12, 2025
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jupiter Endovascular**
Location	Menlo Park, CA, US
Contact	Nicole Barber
510(k) history	1 submissions · 1 cleared · 2025-2025