

K254236 Peel-Away Introducer SheathFeb 9, 2026
42 days to decisionK254236 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k254236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 29, 2025
Decision date	Feb 9, 2026
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	VascuTech Medical, LLC
Location	Oaks, PA, US
Contact	Katy Feeny
Website	https://vascutechmedical.com
510(k) history	1 submissions · 1 cleared · 2026-2026

VascuTech Medical, LLC is a medical device manufacturer specializing in vascular access devices. The company develops and manufactures catheters, dilators, introducers, trocars, tunnelers, and needles for interventional radiology, interventional cardiology, pain management, and urology. VascuTech operates a vertically integrated manufacturing facility in Oaks, Pennsylvania. The company has received FDA 510(k) clearance from total submission. VascuTech's regulatory focus is Cardiovascular devices, with its most recent clearance in 2026. The company maintains active FDA and...