FDA 510(k) Premarket Notification

CLEARED

K241550 Gelweave™ Vascular Prostheses

Feb 27, 2025
272 days to decision

K241550 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k241550/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	May 31, 2024
Decision date	Feb 27, 2025
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vascutek, Ltd.**
Location	Pa49rr Scotland, GB
Contact	Ryan King
Website	http://www.vascutek.com/
510(k) history	26 submissions · 23 cleared · 1991-2025

Vascutek, Ltd. is a global medical device company committed to developing innovative solutions for aortic and peripheral vascular disease. The company operates with a manufacturing facility in Inchinnan, Renfrewshire, Scotland. Now part of Terumo Aortic, the brand continues to advance cardiovascular care worldwide. Vascutek has a strong FDA 510(k) regulatory track record. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1991. All submissions focus on Cardiovascular devices, reflecting the company's specialization in aortic...

REGULATORY CONSULTANT

Consulting firm	**Bolton Medical Inc. (Dba Terumo Aortic)**
Contact	Miriam Paret

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov