FDA 510(k) Premarket Notification

CLEARED

K162803 Gelseal Vascular Grafts, Gelsoft Vascular Grafts, Gelsoft Plus Vascular Grafts

Jul 14, 2017
282 days to decision

K162803 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k162803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Oct 5, 2016
Decision date	Jul 14, 2017
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vascutek, Ltd.**
Location	Pa49rr Scotland, GB
Contact	NEIL MCLACHLAN
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...