FDA 510(k) Premarket Notification

**CLEARED**

# K964959 VASCUTEK TWILLWEAVE VASCULAR GRAFT

Mar 10, 1997
89 days to decision

K964959 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k964959/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent - ST |
| Submission type | Traditional |
| Device classification | Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY) |
| Date received | Dec 11, 1996 |
| Decision date | Mar 10, 1997 |
| Days to decision | 89 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Vascutek, Ltd.** |
| Location | Pa49rr Scotland, GB |
| Contact | TEENA M AUGOSTINO |
| 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...