FDA 510(k) Premarket Notification

# K041528 MODIFICATION TO EPTFE GRAFT

**CLEARED**

Sep 14, 2004
98 days to decision

K041528 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k041528/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY) |
| Date received | Jun 8, 2004 |
| Decision date | Sep 14, 2004 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Vascutek, Ltd.** |
| Location | Pa49rr Scotland, GB |
| Contact | STEVEN ARICK |
| 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...