

**K060142 VASCUTEK GELWEAVE SIENA COLLARED ANTEFLO
AND PLEXUS WITH RADIOPAQUE MARKERS**Feb 7, 2006
19 days to decisionK060142 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k060142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jan 19, 2006
Decision date	Feb 7, 2006
Days to decision	19 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vascutek, Ltd.
Location	Pa49rr Scotland, GB
Contact	KAREN KELSO
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...

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Device record: <https://www.510kdatabase.net/k060142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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