

**K910863 EXTRA SOFT/EXTRA LOW WOVEN VASCULAR PROTHESIS**Apr 1, 1991  
31 days to decisionK910863 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k910863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Mar 1, 1991
Decision date	Apr 1, 1991
Days to decision	31 days
Third-party review	No

**APPLICANT**

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Company	<b>Vascutek, Ltd.</b>
Location	Pa49rr Scotland, GB
Contact	ROSHAN MAINI
Website	<a href="http://www.vascutek.com/">http://www.vascutek.com/</a>
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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