

**K963611 VASCUTEK CARDIOVASCULAR FABRIC: VASCUTEK GELSEAL PATCH,VASCUTEK GELSOFT PATCH,VASCUTEK THIN WALL CAROTID PATCH**Nov 21, 1996  
72 days to decisionK963611 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k963611/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptf, Polypropylene (DXZ)
Date received	Sep 10, 1996
Decision date	Nov 21, 1996
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Vascutek, Ltd.</b>
Location	Pa49rr Scotland, GB
Contact	TEENA M AUGOSTINO
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...