FDA 510(k) Premarket Notification

K081560 VASCUTEK CANNULA GRAFT, MODEL CGS2008S

CLEARED

Feb 10, 2009
252 days to decision

K081560 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k081560/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jun 3, 2008
Decision date	Feb 10, 2009
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

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...