FDA 510(k) Premarket Notification

CLEARED

K052578 BARD G2 FILTER SYSTEM - JUGULAR/SUBCLAVIAN DELIVERY KIT, MODEL RF-320J

Nov 25, 2005
66 days to decision

K052578 · Product code: **DTK** · Cardiovascular
Source: https://www.510kdatabase.net/k052578/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Sep 20, 2005
Decision date	Nov 25, 2005
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bard Peripheral Vascular, Inc.**
Location	Tempe, AZ, US
Contact	GENEVIEVE BALUTOWSKI
Website	https://www.bd.com
510(k) history	34 submissions · 30 cleared · 2004-2026

Bard Peripheral Vascular, Inc. is a medical device manufacturer based in Tempe, Arizona. The company specializes in cardiovascular and surgical devices for minimally invasive procedures. FDA 510(k) regulatory activity spans from 2004 to 2026. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent a dominant category, including PTA balloons, atherectomy systems, and vascular access solutions. The company remains actively engaged in device development, with the latest clearance in 2026. Recent cleared devices reflect expertis...