

**K080668 G2 EXPRESS FILTER SYSTEM-FEMORAL (RF400F)
AND JUGULAR/SUBCLAVIAN (RF400J) DELIVERY KITS**Jul 30, 2008
142 days to decisionK080668 · Product code: **DTK** · Cardiovascular
Source: <https://www.510kdatabase.net/k080668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Mar 10, 2008
Decision date	Jul 30, 2008
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	GENEVIEVE BALUTOWSKI
Website	https://www.bd.com
510(k) history	645 submissions · 609 cleared · 1976-2026

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...