FDA 510(k) Premarket Notification

CLEARED

K143208 Denali Filter System - Femoral Delivery Kit, Denali Filter System - Jugular/Subclavain Delivery Kit

Dec 9, 2014
29 days to decision

K143208 · Product code: **DTK** · Cardiovascular
Source: https://www.510kdatabase.net/k143208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Nov 10, 2014
Decision date	Dec 9, 2014
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	Laurie Sang
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 ...