

**K160866 Denali Filter System - Femoral Delivery Kit, Denali Filter System - Jugular/Subclavian Delivery Kit**Apr 29, 2016  
30 days to decisionK160866 · Product code: **DTK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160866/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Mar 30, 2016
Decision date	Apr 29, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	LAURIE SANG
Website	<a href="https://www.bd.com">https://www.bd.com</a>
510(k) history	644 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 ...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k160866/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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