

**K191143 PowerFlow Implantable Apheresis IV Port**Aug 2, 2019  
94 days to decisionK191143 · Product code: **PTD** · General Hospital  
Source: <https://www.510kdatabase.net/k191143/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subcutaneous Implanted Apheresis Port (PTD)
Date received	Apr 30, 2019
Decision date	Aug 2, 2019
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	Kristen Soodak
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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Device record: <https://www.510kdatabase.net/k191143/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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