

**K851323 AMENDMENT WILLIAM HARVEY H-4300  
CARDIOPULMONARY SU**Aug 12, 1985  
130 days to decisionK851323 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k851323/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Apr 4, 1985
Decision date	Aug 12, 1985
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	CATHERINE V BEATH
Website	<a href="https://www.bd.com">https://www.bd.com</a>
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 ...