

**K042036 AIRGUARD VALVED INTRODUCER**Aug 23, 2004  
25 days to decisionK042036 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k042036/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 29, 2004
Decision date	Aug 23, 2004
Days to decision	25 days
Third-party review	Yes
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	GLENN NORTON
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 ...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Citech</b>
Contact	JAMES MURPHY

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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