

K971421 BARD ISOFLOW BLOOD PUMPMay 14, 1998
393 days to decisionK971421 · Product code: **DWA** · Cardiovascular
Source: <https://www.510kdatabase.net/k971421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Apr 16, 1997
Decision date	May 14, 1998
Days to decision	393 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	SANDRA L PERREAND
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 ...