

**K864235 BARD(R) WM HARVEY(R) BLOOD
OXYGENATOR/MODEL H-1600**Jan 2, 1987
66 days to decisionK864235 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k864235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 28, 1986
Decision date	Jan 2, 1987
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	JOSEPH KICEINA
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 ...