

K853080 WILLIAM HARVEY HYBID OXYGENATOR H-1700Oct 11, 1985
80 days to decisionK853080 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k853080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 23, 1985
Decision date	Oct 11, 1985
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	BOGDAN DZIURZYNSKI
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 ...
