FDA 510(k) Premarket Notification

K831988 INTRAVASCULAR CATHETER

CLEARED

Nov 8, 1983
140 days to decision

K831988 · Product code: **FOS** · General Hospital
Source: https://www.510kdatabase.net/k831988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Umbilical Artery (FOS)
Date received	Jun 21, 1983
Decision date	Nov 8, 1983
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k831988/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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