FDA 510(k) Premarket Notification

K890685 BARD UMBILICAL VESSEL CATHETER

CLEARED

Feb 28, 1989
19 days to decision

K890685 · Product code: **FOS** · General Hospital
Source: https://www.510kdatabase.net/k890685/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Umbilical Artery (FOS)
Date received	Feb 9, 1989
Decision date	Feb 28, 1989
Days to decision	19 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	KEVIN E DALY
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/k890685/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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