FDA 510(k) Premarket Notification

CLEARED

K083675 POWER-TRIALYSIS TRIPLE LUMEN ACUTE DIALYSIS CATHETER

Mar 19, 2009
98 days to decision

K083675 · Product code: **NIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k083675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Triple Lumen, Non-implanted (NIE)
Date received	Dec 11, 2008
Decision date	Mar 19, 2009
Days to decision	98 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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