

K090528 DUET LONG-TERM HEMODIALYSIS CATHETER SYSTEM, DUET LONG-TERM HEMODIALYSIS CATHETER SYSTEM CATHETER REPAIR KITMay 28, 2009
90 days to decisionK090528 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k090528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Feb 27, 2009
Decision date	May 28, 2009
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	JI HYUN KIM
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 ...
