

**K010567 OPTIFLOW CATHETER #5641190 CATHETER ONLY
#5643150 CATHETER KIT #5631000 CATHETERLESS TRAY-
GENERIC (COMBINED WITH CATHETR**Mar 28, 2001
30 days to decisionK010567 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k010567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Feb 26, 2001
Decision date	Mar 28, 2001
Days to decision	30 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	PEGGY KEIFFER
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 ...
