FDA 510(k) Premarket Notification

CLEARED

K011015 CATHETER REPAIR KIT WITH REPLACEMENT CONNECTOR, MODEL 5587000

Jun 22, 2001
79 days to decision

K011015 · Product code: **NFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k011015/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Repair, Catheter, Hemodialysis (NFK)
Date received	Apr 4, 2001
Decision date	Jun 22, 2001
Days to decision	79 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 ...