FDA 510(k) Premarket Notification

CLEARED

K910196 BARD HYDROGEL-COATED DIAGNOSTIC URETHRAL CATHETERS

Mar 27, 1991
70 days to decision

K910196 · Product code: **FGH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k910196/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Double Lumen Female Urethrographic (FGH)
Date received	Jan 16, 1991
Decision date	Mar 27, 1991
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	DONNA J WILSON
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 ...