FDA 510(k) Premarket Notification

K823487 BARD URETERAL STENT

CLEARED

May 27, 1983
185 days to decision

K823487 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k823487/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Nov 23, 1982
Decision date	May 27, 1983
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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