

K043193 BARD INLAYOPTIMA URETERAL STENT WITH SUTUREDec 7, 2004
19 days to decisionK043193 · Product code: **FAD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k043193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Ureteral (FAD)
Date received	Nov 18, 2004
Decision date	Dec 7, 2004
Days to decision	19 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	FRANCES E HARRISON
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 ...