K983498 BARD INLAY LUBRICIOUS DOUBLE PIGTAIL URETERAL STENT WITH SUTURE (HEREINAFTER REFERRED TO AS BARD LUBRICIOUS URETERAL STE

CLEARED

Dec 15, 1998
71 days to decision

K983498 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k983498/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stent, Ureteral (FAD)
Date received	Oct 5, 1998
Decision date	Dec 15, 1998
Days to decision	71 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	GEORGIA C ABERNATHY
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 ...