FDA 510(k) Premarket Notification

K993392 BARD MEMOTHERM FLEXX BILIARY STENT

CLEARED

Jan 6, 2000
90 days to decision

K993392 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k993392/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Abbreviated
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 8, 1999
Decision date	Jan 6, 2000
Days to decision	90 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	CAROL VIERLING
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 ...