FDA 510(k) Premarket Notification

CLEARED

K070558 BARDEX LUBRI-SIL AND BARDEX LUBRI-SIL I.C. ANTI-INFECTIVE ALL-SILICONE FOLEY CATHETERS

Dec 7, 2007
283 days to decision

K070558 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k070558/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Feb 27, 2007
Decision date	Dec 7, 2007
Days to decision	283 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Citech**
Contact	ROBERT MOSENKIS

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov