

**K070508 BARDEX LUBRI-SIL ALL-SILICONE LUBRICIOUS
COATED FOLEY CATHETER 6 FR**Mar 9, 2007
15 days to decisionK070508 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k070508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Feb 22, 2007
Decision date	Mar 9, 2007
Days to decision	15 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	MICHELLE GUDITH
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](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k070508/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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