FDA 510(k) Premarket Notification

K003289 BARDEX LATEX-FREE TEMPERATURE-SENSING FOLEY CATHETER (UNCOATED)

CLEARED

Jan 5, 2001
77 days to decision

K003289 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k003289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Oct 20, 2000
Decision date	Jan 5, 2001
Days to decision	77 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BARDEX LUBRI-SIL TEMPERATURE-SENSING FOLEY CATHETER (LU

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Citech**

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