

K002868 BARD ALL-SILICONE 3-WAY FOLEY CATHETERDec 8, 2000
86 days to decisionK002868 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k002868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Sep 13, 2000
Decision date	Dec 8, 2000
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BARD LUBRI-SIL 3-WAY FOLEY CATHETER; BARD LUBRI-SIL I.C. 3-WAY FOLEY CATHETER

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	ANGELA L BUNN
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 ...