

**K040504 BARDEX, LUBRI-SIL AND LUBRI-SIL IC ALL-SILICONE
FOLEY CATHETERS**May 14, 2004
77 days to decisionK040504 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k040504/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received | Feb 27, 2004 |
| Decision date | May 14, 2004 |
| Days to decision | 77 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 | JOHN C KNORPP |
| 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 ...