

K910318 BARD(R) HYDROGEL/SILVER-COATED FOLEY CATHETERAug 18, 1994
1302 days to decisionK910318 · Product code: **MJC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k910318/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Urological (antimicrobial) And Accessories (MJC) |
| Date received | Jan 24, 1991 |
| Decision date | Aug 18, 1994 |
| Days to decision | 1302 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | C.R. Bard, Inc. |
| Location | Covington, GA, US |
| Contact | DONNA J WILSON |
| 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 ...