

K780032 URINARY LEG BAGJan 17, 1978
8 days to decisionK780032 · Product code: **FAQ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k780032/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bag, Urine Collection, Leg, For External Use, Sterile (FAQ) |
| Date received | Jan 9, 1978 |
| Decision date | Jan 17, 1978 |
| Days to decision | 8 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | C.R. Bard, Inc. |
| Location | Covington, GA, US |
| 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 ...
