FDA 510(k) Premarket Notification

**CLEARED**

# K090101 EQUISTREAM LONG-TERM HEMODIALYSIS CATHETERS

Feb 10, 2009
26 days to decision

K090101 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k090101/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent - K |
| Submission type | Special |
| Device classification | Catheter, Hemodialysis, Implanted (MSD) |
| Date received | Jan 15, 2009 |
| Decision date | Feb 10, 2009 |
| Days to decision | 26 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 | JESSICA AGNELLO |
| 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 ...