

K780409 COLOPLAST-DURASEAL OSTOMY APPLIANCEApr 27, 1978
45 days to decisionK780409 · Product code: **EZS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k780409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Colostomy, Disposable (EZS)
Date received	Mar 13, 1978
Decision date	Apr 27, 1978
Days to decision	45 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 ...
