

**K050875 U-BALLOON DILATION CATHETER**May 26, 2005  
50 days to decisionK050875 · Product code: **EZN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k050875/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Apr 6, 2005
Decision date	May 26, 2005
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	JOHN C KNORPP
Website	<a href="https://www.bd.com">https://www.bd.com</a>
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 ...