

**K080944 X-FORCE NEPHROSTOMY BALLOON DILATION  
CATHETER**Oct 23, 2008  
203 days to decisionK080944 · Product code: **LJE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k080944/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Nephrostomy (LJE)
Date received	Apr 3, 2008
Decision date	Oct 23, 2008
Days to decision	203 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	TERRI MORRIS
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 ...