

K081288 ASPIRA PERITONEAL DRAINAGE SYSTEMJul 18, 2008
72 days to decisionK081288 · Product code: **PNG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k081288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	May 7, 2008
Decision date	Jul 18, 2008
Days to decision	72 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	HENRY BOLAND
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 ...