

K241946 PeritX™ 1L Drainage Kit (90-1010)Dec 6, 2024
156 days to decisionK241946 · Product code: **PNG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peritoneal, Drainage Catheter For Refractory Ascites, Long-term Indwelling (PNG)
Date received	Jul 3, 2024
Decision date	Dec 6, 2024
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PeritX™ 2L Drainage Kit (90-2010); PeritX™ Peritoneal Catheter Kit (50-9000C); PeritX™ Peritoneal Catheter and Starter Kit (50-9900C); PeritX™ Peritoneal Catheter Mini Kit (50-9050A); PleurX™ Low Profile Catheter Mini Kit (50-8050); Valve Cap (50-7235A); PeritX™ Valve Kit (50-7272); Catheter Access Kit (50-7280A); Lockable Drainage Line (50-7245A); Lockable Drainage Line Kit (50-7265A); PleurX™ Supplemental Insertion Kit (50-7262); Procedure Pack (50-

APPLICANT

Company	Bard Peripheral Vascular, Inc.
Location	Tempe, AZ, US
Contact	Gabrielle Wipper
Website	https://www.bd.com
510(k) history	34 submissions · 30 cleared · 2004-2026

Bard Peripheral Vascular, Inc. is a medical device manufacturer based in Tempe, Arizona. The company specializes in cardiovascular and surgical devices for minimally invasive procedures. FDA 510(k) regulatory activity spans from 2004 to 2026. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent a dominant category, including PTA balloons, atherectomy systems, and vascular access solutions. The company remains actively engaged in device development, with the latest clearance in 2026. Recent cleared devices reflect expertis...

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