CLEARED

K232737 PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port

Dec 8, 2023
92 days to decision

K232737 · Product code: **LJT** · General Hospital
Source: https://www.510kdatabase.net/k232737/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Sep 7, 2023
Decision date	Dec 8, 2023
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port; PowerPort™ Slim ECG Enabled Implantable Port

APPLICANT

Company	**Bard Peripheral Vascular, Inc.**
Location	Tempe, AZ, US
Contact	Kristen Ortiz
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...