

K192318 Ultraverse 014 and 018 PTA Balloon Dilatation Catheters

Oct 3, 2019
38 days to decisionK192318 · Product code: **LIT** · Cardiovascular
Source: <https://www.510kdatabase.net/k192318/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 26, 2019
Decision date	Oct 3, 2019
Days to decision	38 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Bard Peripheral Vascular, Inc.
Location	Tempe, AZ, US
Contact	Andrew Quach
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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Device record: <https://www.510kdatabase.net/k192318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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