FDA 510(k) Premarket Notification

CLEARED

K131199 ULTRAVERSE RX PTA BALLOON DILATATION CATHETER

May 30, 2013
34 days to decision

K131199 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k131199/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 26, 2013
Decision date	May 30, 2013
Days to decision	34 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Bard Peripheral Vascular, Inc.**
Location	Tempe, AZ, US
Contact	MARIO THOMAS
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...