

**K133569 TRUE DILATATION BALLOON VALVULOPLASTY
CATHETER, 20MM X 4.5 CM, 22MM X 4.5CM, 24 MM X 4.5CM,
26MM X 4.5CM**Dec 20, 2013
30 days to decisionK133569 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k133569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Nov 20, 2013
Decision date	Dec 20, 2013
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bard Peripheral Vascular, Inc.
Location	Tempe, AZ, US
Contact	TIFFINI DIAGE
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...