

K141985 TRUE BA V BALLOON VALVULOPLASTY CATHETERSep 18, 2014
58 days to decisionK141985 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k141985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Jul 22, 2014
Decision date	Sep 18, 2014
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	AARON CONOVALOFF
Website	https://www.bd.com
510(k) history	645 submissions · 609 cleared · 1976-2026

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...
