CLEARED

K212588 Conquest 40 PTA Dilatation Catheter, Atlas Gold PTA Dilatation Catheter, Vida PTV Dilatation Catheter, Vida BAV Balloon Valvuloplasty Catheter

May 4, 2022
261 days to decision

K212588 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k212588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 16, 2021
Decision date	May 4, 2022
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**C.R. Bard, Inc.**
Location	Covington, GA, US
Contact	Arieona Boyle
Website	https://www.bd.com
510(k) history	644 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 ...