FDA 510(k) Premarket Notification

# K250219 Dorado™ PTA Balloon Dilatation Catheter

**CLEARED**

Jun 17, 2025
144 days to decision

K250219 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k250219/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Jan 24, 2025 |
| Decision date | Jun 17, 2025 |
| Days to decision | 144 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Bard Peripheral Vascular, Inc.** |
| Location | Tempe, AZ, US |
| Contact | Joan Bergstrom |
| 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...