

K072283 DORADO PTA BALLOON DILATATION CATHETERSep 19, 2007
34 days to decisionK072283 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k072283/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Aug 16, 2007 |
| Decision date | Sep 19, 2007 |
| Days to decision | 34 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------------------|
| Company | Bard Peripheral Vascular, Inc. |
| Location | Tempe, AZ, US |
| Contact | GENEVIEVE BALUTOWSKI |
| 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...
