FDA 510(k) Premarket Notification

CLEARED

K171953 Bard Mission Disposable Core Biopsy Instrument

Sep 14, 2017
77 days to decision

K171953 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jun 29, 2017
Decision date	Sep 14, 2017
Days to decision	77 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Bard Peripheral Vascular, Inc.**
Location	Tempe, AZ, US
Contact	Susan Sheffield
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...