CLEARED

K133948 BARD(R) MONOPTY(R) DISPOSABLE CORE BIOPSY INSTRUMENT, BARD(R) MAX-CORE(R) DISPOSABLE CORE INSTRUMENT

Feb 21, 2014
60 days to decision

K133948 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k133948/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Dec 23, 2013
Decision date	Feb 21, 2014
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bard Peripheral Vascular, Inc.**
Location	Tempe, AZ, US
Contact	SARAH MCCARTNEY
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...