

**K192948 EleVation Breast Biopsy Driver, EleVation Breast Biopsy Probe - 10G, EleVation Breast Biopsy Probe - 14G**Nov 7, 2019  
20 days to decisionK192948 · Product code: **KNW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192948/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Oct 18, 2019
Decision date	Nov 7, 2019
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bard Peripheral Vascular, Inc.</b>
Location	Tempe, AZ, US
Contact	Meghan McKelvey
Website	<a href="https://www.bd.com">https://www.bd.com</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k192948/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026