

**K243642 UltraCor™ Twirl™ Breast Tissue Marker**Mar 24, 2025  
118 days to decisionK243642 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243642/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Nov 26, 2024
Decision date	Mar 24, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	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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Device record: <https://www.510kdatabase.net/k243642/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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