

K152510 UltraCor Twirl Breast Tissue MarkerMay 13, 2016
254 days to decisionK152510 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k152510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Sep 2, 2015
Decision date	May 13, 2016
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bard Peripheral Vascular, Inc.
Location	Tempe, AZ, US
Contact	KRISTEN DEJEU
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...
