FDA 510(k) Premarket Notification

**CLEARED**

# K180061 UltraCor Twirl Breast Tissue Marker

Mar 9, 2018
60 days to decision

K180061 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180061/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received | Jan 8, 2018 |
| Decision date | Mar 9, 2018 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Bard Peripheral Vascular, Inc.** |
| Location | Tempe, AZ, US |
| Contact | Meghan McKelvey |
| 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...