

**K123911 SENOMARK ULTRA BREAST TISSUE MARKER**Jan 10, 2013  
22 days to decisionK123911 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k123911/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received         | Dec 19, 2012                            |
| Decision date         | Jan 10, 2013                            |
| Days to decision      | 22 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>C.R. Bard, Inc.</b>                              |
| Location       | Covington, GA, US                                   |
| Contact        | SARAH MCCARTNEY                                     |
| Website        | <a href="https://www.bd.com">https://www.bd.com</a> |
| 510(k) history | 645 submissions · 609 cleared · 1976-2026           |

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...

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