

K251989 VizMark Preloaded Tissue Marker Device (VM-0001)Dec 12, 2025
168 days to decisionK251989 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251989/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received | Jun 27, 2025 |
| Decision date | Dec 12, 2025 |
| Days to decision | 168 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Breast-Med, Inc. |
| Location | Golden Valley, MN, US |
| Contact | Michael Nelson |
| 510(k) history | 2 submissions · 2 cleared · 2015-2025 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Carbon Medical Technologies, Inc. |
| Contact | Yidi Hou |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251989/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026