

**K243271 MENTOR™ MemoryShape™ Resterilizable Gel Breast Implant Sizer**Jan 13, 2025  
89 days to decisionK243271 · Product code: MRD · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243271/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Mammary Sizer (MRD)   |
| Date received         | Oct 16, 2024  |
| Decision date         | Jan 13, 2025  |
| Days to decision      | 89 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |
| Other names           | MENTOR™ MemoryGel™ Resterilizable Gel Breast Implant Sizer; MENTOR™ MemoryGel™ Enhance Single Use Gel Sizer |

**APPLICANT**

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|----------------|---|
| Company        | <b>Mentor Worldwide, LLC</b>                                      |
| Location       | Santa Barbara, CA, US   |
| Contact        | Saakshi Arora-Tice  |
| Website        | <a href="http://www.mentorwllc.com">http://www.mentorwllc.com</a> |
| 510(k) history | 12 submissions · 12 cleared · 2013-2025                           |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243271/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026