

K241552 MENTOR™ MemoryGel™ Enhance Single Use Gel SizerSep 6, 2024
98 days to decisionK241552 · Product code: **MRD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241552/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mammary Sizer (MRD) |
| Date received | May 31, 2024 |
| Decision date | Sep 6, 2024 |
| Days to decision | 98 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Mentor Worldwide, LLC |
| Location | Santa Barbara, CA, US |
| Contact | Alicia Botham |
| Website | http://www.mentorwwllc.com |
| 510(k) history | 12 submissions · 12 cleared · 2013-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241552/> 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 13, 2026