

**K211972 Omeza Collagen Matrix**Sep 1, 2021  
69 days to decisionK211972 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211972/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Dressing, Wound, Drug (FRO)        |
| Date received         | Jun 24, 2021                       |
| Decision date         | Sep 1, 2021                        |
| Days to decision      | 69 days                            |
| Third-party review    | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Omeza, LLC</b>                     |
| Location       | Sarasota, FL, US                      |
| Contact        | Thomas Gardner                        |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------|
| Consulting firm | <b>Hogan Lovells US LLP</b> |
| Contact         | Randy Prebula               |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211972/> 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 26, 2026