

**K942366 LORREX GAUZE SPONGES, X-RAY DETECTABLE**May 27, 1994  
9 days to decisionK942366 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k942366/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Gauze/sponge, Internal, X-ray Detectable (GDY) |
| Date received         | May 18, 1994                                   |
| Decision date         | May 27, 1994                                   |
| Days to decision      | 9 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Lorrex Health Products</b>           |
| Location       | Secaucus, NJ, US                        |
| Contact        | ERIC MORALES                            |
| 510(k) history | 16 submissions · 16 cleared · 1993-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k942366/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 6, 2026