

**K092647 LENSX 550 LASER SYSTEM**Dec 11, 2009  
106 days to decisionK092647 · Product code: **OOE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k092647/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ophthalmic Femtosecond Laser (OOE) |
| Date received         | Aug 27, 2009                       |
| Decision date         | Dec 11, 2009                       |
| Days to decision      | 106 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Lensx Lasers, Inc.</b>             |
| Location       | Laguna Beach, CA, US                  |
| Contact        | Judy Gordon                           |
| 510(k) history | 4 submissions · 4 cleared · 2009-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092647/> 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 June 20, 2026