

**K931478 ZEISS OPMI L STEREO-LAPAROSCOPE**Sep 28, 1994  
553 days to decisionK931478 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k931478/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Laparoscope, Gynecologic (and Accessories) (HET) |
| Date received         | Mar 24, 1993                                     |
| Decision date         | Sep 28, 1994                                     |
| Days to decision      | 553 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Carl Zeiss, Inc.</b>                 |
| Location       | Mchenry, IL, US                         |
| Contact        | CHRISTOPHER TALBOT                      |
| 510(k) history | 44 submissions · 44 cleared · 1980-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931478/> 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 May 20, 2026