

**K924523 HYS-SURGIFLATOR**Apr 11, 1995  
945 days to decisionK924523 · Product code: **HIG** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k924523/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Insufflator, Hysteroscopic (HIG)   |
| Date received         | Sep 8, 1992                        |
| Decision date         | Apr 11, 1995                       |
| Days to decision      | 945 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>W.O.M. World of Medicine GmbH</b>    |
| Location       | Tucson, AR, US                          |
| Contact        | OWEN B LAMB                             |
| 510(k) history | 26 submissions · 26 cleared · 1992-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924523/> 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 29, 2026