

**K925691 INSUFFLATION TUBING**Sep 23, 1993  
315 days to decisionK925691 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k925691/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Insufflator, Laparoscopic (HIF)    |
| Date received         | Nov 12, 1992                       |
| Decision date         | Sep 23, 1993                       |
| Days to decision      | 315 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mectra Labs, Inc.</b>              |
| Location       | Bloomfield, IN, US                    |
| Contact        | THOMAS P CLEMENT                      |
| 510(k) history | 9 submissions · 9 cleared · 1992-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k925691/> 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 14, 2026