

**K915388 LAPAROSCOPIC MYOMA SCREW**May 18, 1992  
171 days to decisionK915388 · Product code: **HHO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k915388/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Screw, Fibroid, Gynecological (HHO) |
| Date received         | Nov 29, 1991                        |
| Decision date         | May 18, 1992                        |
| Days to decision      | 171 days                            |
| Third-party review    | No                                  |
| Summary / Statement   | Statement                           |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cook Urological, Inc.</b>              |
| Location       | Spencer, IN, US                           |
| Contact        | MICHELLE YOUNG                            |
| 510(k) history | 104 submissions · 102 cleared · 1986-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915388/> 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 19, 2026