

**K080525 COOK ODYSSEY HOLMIUM LASER SYSTEM, MODEL 30W**Apr 17, 2008  
51 days to decisionK080525 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k080525/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Feb 26, 2008                            |
| Decision date         | Apr 17, 2008                            |
| Days to decision      | 51 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Cook Urological, Inc.</b>              |
| Location       | Spencer, IN, US                           |
| Contact        | CINDY FOOTE                               |
| 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/k080525/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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