

**K013471 DELTA 2000 SERIES EXTRACORPOREAL  
LITHOTRIPTER**Apr 29, 2002  
193 days to decisionK013471 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k013471/>**SUBMISSION DETAILS**

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|                       |                                                           |
|-----------------------|-----------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional                                               |
| Device classification | Lithotripter, Extracorporeal Shock-wave, Urological (LNS) |
| Date received         | Oct 18, 2001                                              |
| Decision date         | Apr 29, 2002                                              |
| Days to decision      | 193 days                                                  |
| Third-party review    | No                                                        |
| Summary / Statement   | Summary                                                   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>E.S.W.L. Products, Inc.</b>        |
| Location       | Deer Field, IL, US                    |
| Contact        | DANIEL KAMM                           |
| 510(k) history | 1 submissions · 1 cleared · 2002-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013471/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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