

**K022817 COOLTOUCH ND:YAG LASER SYSTEM, MODEL COOLTOUCH, COOLTOUCH-II ND:YAG LASER SYSTEM, MODEL COOLTOUCH-II**Nov 22, 2002  
88 days to decisionK022817 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k022817/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Aug 26, 2002                            |
| Decision date         | Nov 22, 2002                            |
| Days to decision      | 88 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Icn Pharmaceuticals, Inc.</b>        |
| Location       | Walker, MI, US                          |
| Contact        | EDWARD F SMITH                          |
| 510(k) history | 30 submissions · 30 cleared · 1977-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k022817/>; 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 May 26, 2026