

**K030846 CANDELA SMOOTHBEAM LASER SYSTEM**Sep 16, 2003  
183 days to decisionK030846 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k030846/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Mar 17, 2003                            |
| Decision date         | Sep 16, 2003                            |
| Days to decision      | 183 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Candela Corp.</b>                    |
| Location       | Natick, MA, US                          |
| Contact        | LORRAINE CALZETTA PATROVIC              |
| 510(k) history | 48 submissions · 48 cleared · 1986-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030846/> 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 18, 2026