

**K083889 FOTONA QX ND:YAG/KTP LASER SYSTEM FAMILY**Apr 23, 2009  
115 days to decisionK083889 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083889/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Dec 29, 2008                            |
| Decision date         | Apr 23, 2009                            |
| Days to decision      | 115 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Fotona D.D.</b>                      |
| Location       | Ljubljana, SI                           |
| Contact        | STOJAN TROST                            |
| 510(k) history | 27 submissions · 27 cleared · 1998-2015 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083889/> 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 4, 2026