

K991632 FOTONA NOVALIS ER: YAG LASER SYSTEMAug 10, 1999
90 days to decisionK991632 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k991632/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | May 12, 1999 |
| Decision date | Aug 10, 1999 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fotona D.D. |
| Location | Ljubljana, SI |
| Contact | MOJCA VALIJAVEC |
| 510(k) history | 27 submissions · 27 cleared · 1998-2015 |

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