

**K002884 PARADIGM-FOTONA YAPLASE ND:YAP LASER  
SYSTEM AND ACCESSORIES**Dec 4, 2000  
80 days to decisionK002884 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k002884/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 15, 2000
Decision date	Dec 4, 2000
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002884/> Data sourced from FDA 510(k) public records (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. - Generated July 3, 2026