

**K132806 FOTONA F-22 LASER HANDPIECE (F-RUNNER),
FOTONA FS-01 LASER HANDPIECE**

Jul 11, 2014
308 days to decision

K132806 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k132806/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 6, 2013
Decision date	Jul 11, 2014
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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