K070355 FOTONA FIDELIS III ER:YAG/ND:YAG LASER SYSTEM FAMILY

CLEARED

Mar 4, 2008
392 days to decision

K070355 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k070355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 6, 2007
Decision date	Mar 4, 2008
Days to decision	392 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