

K183307 Magma Spark Pro (Magma Spark Plus, Alpha)Dec 11, 2018
13 days to decisionK183307 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 28, 2018
Decision date	Dec 11, 2018
Days to decision	13 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Formatk Systems , Ltd.
Location	Tirat Carmel, IL
Contact	Amit Goren
510(k) history	4 submissions · 4 cleared · 2016-2018

REGULATORY CONSULTANT

Consulting firm	A. Stein - Regulatory Affairs Consulting , Ltd.
Contact	Amit Goren

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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