

**K162781 Magma Spark**Nov 9, 2016  
37 days to decisionK162781 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162781/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 3, 2016
Decision date	Nov 9, 2016
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Formatk Systems , Ltd.</b>
Location	Tirat Carmel, IL
Contact	Ahava Stein
510(k) history	4 submissions · 4 cleared · 2016-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162781/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026