

K153566 Magma SystemApr 6, 2016
114 days to decisionK153566 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k153566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 14, 2015
Decision date	Apr 6, 2016
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153566/> 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 June 28, 2026