Formatk Systems Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str. Suite 102
Kfar Saba, 4442520 Il

December 11, 2018

Re: K183307
Trade/Device Name: Magma Spark Pro (Magma Spark Plus, Alpha)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, ONF
Dated: November 25, 2018
Received: November 28, 2018

Dear Amit Goren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Neil R.P. Ogden

Digitally signed by Neil R.P. Ogden
Date: 2018.12.11 08:44:42 -05'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183307

Device Name
Magma Spark Pro

Indications for Use *(Describe)*

The Magma Spark Pro system intended use is for non-invasive aesthetic and cosmetic treatments.
The Magma Spark Pro system has connection capability with the following available treatment hand pieces, for multi-application treatment options. All hand pieces are designed for aesthetic and dermatological skin procedure applications, as follows:

• Magma Spark Pro system with ALD/LLD Laser hand piece is indicated for:
o Hair removal
o Permanent hair reduction * in skin type I-VI
o Pseudofolliculitis Barbae (PFB)

• Magma Spark Pro system with Intense Pulsed Light (IPL) Hand pieces (5 different Applicators) with a spectrum of 430-1100nm is intended for:

o Magma Spark Pro system with L-650 (650-1100nm) IPL hand piece is indicated for:
▪ Removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction * in skin types I-V through selective targeting of melanin in hair follicles.
▪ Benign epidermal lesions, including dyschromia, hyperpigmentation

o Magma Spark Pro system with S-590 (590-1100nm) IPL hand piece is indicated for:
▪ Removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction * in skin types I-IV through selective targeting of melanin in hair follicles.
▪ Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles)
▪ Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins, venous malformations.

o Magma Spark Pro system with L-530 (530-1100nm) IPL hand piece is indicated for:
▪ Benign epidermal lesions, including dyschromia, hyperpigmentation, ephelides (freckles)
▪ Cutaneous lesions, including warts, scars and striae
▪ Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

o Magma Spark Pro system with S-530 (530-1100nm) IPL hand piece is indicated for:
▪ Mild to moderate inflammatory Acne (Acne vulgaris)
▪ Benign epidermal lesions, including dyschromia, hyperpigmentation, ephelides (freckles)
▪ Cutaneous lesions, including warts, scars and striae
▪ Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations

o Magma Spark Pro system with S-430 (430-1100nm) IPL hand piece is indicated for:
▪ Mild to moderate inflammatory Acne (Acne vulgaris)

Note * Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 6:

Special 510(k) Summary

510(K) SUMMARY

MAGMA SPARK PRO DEVICE

510(k) Number K183307

Applicant Name:

Company Name: Formatk Systems Ltd.
Address: 3 Hayozma St.
Tirat Hacarmel, 3903203, Israel
Tel: +972-4-8571848
Fax: +972-4-8570810
E-mail: amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
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E-mail: amit@asteinrac.com

Date Prepared: December 09, 2018

Trade Name: Magma Spark Pro (Additional proprietary names: Magma Spark Plus / Alpha)

Classification Name: 21 CFR Classification section 878.4810

Product Code & Common Names: GEX - Powered Laser Surgical Instrument,
ONF - Powered Light Based Non-Laser Surgical Instrument with Thermal Effect

Classification: Class II Medical Device

Predicate Device:

The Magma Spark Pro device is substantially equivalent to the previously cleared, Magma device, also manufactured by Formatk Systems Ltd and the subject of 510(k)

document K153566. Additional features of the Magma Spark Pro System are substantially equivalent to the Lumenis M22 & ResurFx (manufactured by Lumenis Ltd. and the subject of 510(k) document K170060).

Device name	**Manufacturer**	**510(k) No.**
Magma	Formatk Systems Ltd.	K153566
M22 & ResurFX Systems	Lumenis Ltd.	K170060

Device Description:

The Magma Spark Pro device is a computerized, multi-application, compatible system platform designed to provide laser and intense pulsed light (IPL) optical energies for non-invasive aesthetic dermatology procedures.

The Magma Spark Pro is a relatively small tabletop device (portable version is also available). The device is compatible with two diode laser applicators (ALD and LLD) at nominal 808 nm wavelength and five IPL applicators: S-430, S-530, S-590, L-530 and L-650 at a wavelength range of 430-1100 nm. The system platform includes an AC/DC safety approved power supply, a CPU board, a Laser driver board, a charging board, a simmer board, an LCD display, Wires connectors and control components (inlet with On/Off switch and fuses, Emergency button), footswitch panel, water based cooling system for IPL and Laser applicators cooling and a touch screen module. The operator of Magma Spark Pro chooses and monitors the mode and intensity of the treatment from a digital control panel on the front of the device. Melanin meter is provided as an accessory tool for skin type determination.

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Input Current (A)	Max. 7.8A
Platform dimensions (inch)	24.8”W×21.7”D×21.7”H
Platform weight (lb.)	50.7lbs.
Platform dimensions + Cart (inch)	24.8”W×21.7”D×43.4”H
Platform + Cart weight (lb.)	84.5lbs.
ALD & LLD Diode laser wavelength (nm)	808
IPL Applicators wavelength:	
S-430 Applicator wavelength (nm)	430-1100
S-530 Applicator wavelength (nm)	530-1100
L-530 Applicator wavelength (nm)	530-1100
S-590 Applicator wavelength (nm)	590-1100
L-650 Applicator wavelength (nm)	650-1100

Maximal Fluence (J/cm^2):	
ALD	Up to 75
LLD	Up to 28
S-430 Applicator	Up to 45J/cm^2
S-530 Applicator	Up to 45J/cm^2
L-530 Applicator	Up to 35J/cm^2
S-590 Applicator	Up to 45J/cm^2
L-650 Applicator	Up to 35J/cm^2

Intended Use/Indication for Use:

The Magma Spark Pro system intended use is for non-invasive aesthetic and cosmetic treatments.

The Magma Spark Pro system has connection capability with the following available treatment hand pieces, for multi-application treatment options. All hand pieces are designed for aesthetic and dermatological skin procedure applications, as follows:

- Magma Spark Pro system with ALD/LLD Laser hand piece is indicated for:
  - Hair removal
  - Permanent hair reduction * in skin type I-VI
  - Pseudofolliculitis Barbae (PFB)

- Magma Spark Pro system with Intense Pulsed Light (IPL) Hand pieces (5 different Applicators) with a spectrum of 430-1100nm is intended for:

  Magma Spark Pro system with L-650 (650-1100nm) IPL hand piece is indicated for:
  - Removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction * in skin types I-V through selective targeting of melanin in hair follicles.
  - Benign epidermal lesions, including dyschromia, hyperpigmentation

  Magma Spark Pro system with S-590 (590-1100nm) IPL hand piece is indicated for:
  - Removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction * in skin types I-IV through selective targeting of melanin in hair follicles.

- Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles)
- Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins, venous malformations.

Magma Spark Pro system with L-530 (530-1100nm) IPL hand piece is indicated for:

- Benign epidermal lesions, including dyschromia, hyperpigmentation, ephelides (freckles)
- Cutaneous lesions, including warts, scars and striae
- Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

Magma Spark Pro system with S-530 (530-1100nm) IPL hand piece is indicated for:

- Mild to moderate inflammatory Acne (Acne vulgaris)
- Benign epidermal lesions, including dyschromia, hyperpigmentation, ephelides (freckles)
- Cutaneous lesions, including warts, scars and striae
- Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations

Magma Spark Pro system with S-430 (430-1100nm) IPL hand piece is indicated for:

- Mild to moderate inflammatory Acne (Acne vulgaris)

Note * Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Performance Standards:

Magma Spark Pro complies with the following FDA recognized consensus standards:

- IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance (2005 +Am.1 2012, 3rd Ed.).
- IEC 60601-1-2 Medical electrical equipment Part 1-2: Collateral Standard: Electromagnetic compatibility -Requirements and tests (2014, 4th Ed.).
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for safety – Collateral Standard: Usability (2010 + A1:2013, Ed. 3.1).
- IEC 60601-2-22 Medical Electrical Equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (2007, 3rd Ed. + A1:2012).
- IEC 60601-2-57 Medical Electrical Equipment Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use (2011, 1st Ed.).
- IEC 60825-1 Safety of laser products Part 1: Equipment classification and requirements (2014, 3rd Ed.).
- IEC 62304 Medical device software: Software life-cycle processes (2006, 1st Ed. + A1:2015).

Non-Clinical (Bench) Performance Data:

The underlying technology and principle of operation of Magma Spark Pro is essentially the same as the predicate device. Therefore, apart to the performance testing conducted in adherence with the aforementioned recognized consensus standards, no additional testing was performed to sustain device safety and effectiveness. Comprehensive software-system test plan and results report covers the full system test of the Magma Spark Pro. It includes operation and user procedures, as well as programs in addition to comprehensively testing firmware functionality, hardware interfaces, performance, load test, download procedure, integrity, recovery and usability.

Pre-Clinical (Animal Study) Performance Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The below table summarizes the main comparison aspects between the Magma Spark Pro and its proposed predicate devices; the Magma device (FDA cleared in K153566) and M22 & ResurFx Systems (FDA cleared in K170060).

	Magma Spark Pro (modified device; Formatk Systems Ltd.)	**Magma K153566** (cleared device; Formatk Systems Ltd.)	**M22 & ResurFX Systems K170060** (reference device; Lumenis Ltd.)
Device Classification			
Product Code	GEX, ONF	GEX, ONF	GEX, ONF, ONG
Class	Class II	Class II	Class II
Device Technological Characteristics			
Energy Used / Delivered	• Intense Pulsed Light (IPL; 430-1100nm) • Diode laser (808nm nominal)	• Intense Pulsed Light (IPL; 430-1100nm) • Diode laser (808nm nominal) • Nd:YAG laser (1064nm)	• Intense Pulsed Light (IPL; 400-1200nm)
Main Unit and Controller			
Performance specifications	Input power: 100-240V, 50-60Hz 7.8A max.	Input power: 100-240V, 50-60Hz 9.5A max.	Input power: 100-240V, 50/60 Hz, 15A max.
Physical specifications	Dimensions: 63cmW×55cmD×55cmH [24.8”W×21.7”D×21.7”H] Weight: 27 Kg (50.7lbs.) Magma Spark Pro (+ Cart): 63cmW×55cmD×110cmH [24.8”W×21.7”D×43.4”H] Weight: 45kg (84.5lbs.)	Dimensions: 40cmW×53cmD×119cmH [15.9’’W×21’’D×47.2’’H] Weight: 34 Kg (74.8lbs.)	Dimensions: 40cmW x 40cmD x 100cmH [16’’Wx16’’D x39’’H] Weight: 75 Kg (165 lbs.)
Diode Laser Applicators			

	Magma Spark Pro (modified device; Formatk Systems Ltd.)	**Magma K153566** (cleared device; Formatk Systems Ltd.)	**M22 & ResurFX Systems K170060** (reference device; Lumenis Ltd.)
Performance specifications	*ALD Applicator:* • Nominal wavelength: 808nm • Tip size: 10×12mm • Fluence: Up to 75J/cm^2 • Pulse duration: 8 to 400msec • Pulse repetition rate: up to 10Hz *LLD Applicator:* • Nominal wavelength: 808nm • Tip size: 30×15mm • Fluence: Up to 28J/cm^2 • Pulse duration: 25 to 400msec • Pulse repetition rate: up to 3Hz	*ALD Applicator:* • Nominal wavelength: 808nm • Tip size: 10×12mm • Fluence: Up to 75J/cm^2 • Pulse duration: 8 to 400msec • Pulse repetition rate: up to 10Hz *LLD Applicator:* • Nominal wavelength: 808nm • Tip size: 30×15mm • Fluence: Up to 35J/cm^2 • Pulse duration: 25 to 400msec • Pulse repetition rate: up to 4Hz	
Physical specifications	ALD Weight: 1.5kg (3.3lb) LLD 1.5kg (3.3lb)	ALD Weight: 1.5kg (3.3lb) LLD 1.5kg (3.3lb)	
Intense Pulsed Light (IPL) Applicators			
Performance specifications and Operation Parameters	S-430 Applicator Wavelength spectrum: 430-1100nm Tip Size: 2cm^2 Fluence: Up to 45J/cm^2 Pulse duration: max 50msec	F-AC Applicator Wavelength spectrum: 430-1100nm Tip size: 1.6 cm^2 Fluence: Up to 21.8J/cm^2 Pulse duration: max 6msec	The Universal IPL hand piece has ten (10) different filters available: Cut-off filters of 515,560, 590,615, 640, 695 and 755 nm,

	Magma Spark Pro (modified device; Formatk Systems Ltd.)	**Magma K153566** (cleared device; Formatk Systems Ltd.)	**M22 & ResurFX Systems K170060** (reference device; Lumenis Ltd.)
	S-530 Applicator Wavelength spectrum: 530-1100nm Tip Size: 2cm^2 Fluence: Up to 45J/cm^2 Pulse duration max 50msec L-530 Applicator Wavelength spectrum: 530-1100nm Tip Size: 5cm^2 Fluence: Up to 35J/cm^2 Pulse duration: max 50msec N/A S-590 Applicator Wavelength spectrum: 590-1100nm Tip Size: 2cm^2 Fluence: Up to 45J/cm^2 Pulse duration: max 50msec N/A N/A <u>L-650</u> Applicator Wavelength spectrum: 650-1100nm Tip Size: 5cm^2 Fluence: Up to 35J/cm^2	F-SR Applicator Wavelength spectrum: 530-1100nm Tip size: 1.6 cm^2 Fluence: Up to 21.8J/cm^2 Pulse duration: max 6msec SR Applicator Wavelength spectrum: 530-1100nm Tip size: 6.5 cm^2 Fluence: Up to 21.8J/cm^2 Pulse duration: max 55msec B-SR Applicator F-HR Applicator Wavelength spectrum: 590-1100nm Tip size: 1.6 cm^2 Fluence: Up to 20.2J/cm^2 Pulse duration: max 6msec HR Applicator B-HR Applicator HR* Applicator Wavelength spectrum: 650-1100nm Tip size: 6.5 cm^2 Fluence: Up to 19J/cm^2	Notch Filters of 400-600 & 800-1200 nm and 530-650 & 900-1200 nm and a Narrow band filter of 525-585 nm. Max Fluence: Up to 35 or 56 J/cm^2, upon tip size. The higher 56J/cm^2 is supported by Lumenis 510(k) number K020839.

	Magma Spark Pro (modified device; Formatk Systems Ltd.)	**Magma K153566** (cleared device; Formatk Systems Ltd.)	**M22 & ResurFX Systems K170060** (reference device; Lumenis Ltd.)
	Pulse duration: max 50msec N/A N/A	Pulse duration: max 55msec F-HR* Applicator B-HR*Applicator	
Physical specifications	Weight: 1.6Kg Cord length:1.6m	Weight: 1.6Kg Cord length:1.6m	
Safety and adherence to standards			
Standards Met	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-22 • IEC 60601-2-57 • IEC 60825-1	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-22 • IEC 60601-2-57 • IEC 60825-1	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-57

The components of modified Magma Spark Pro device, similarly to predicate Magma device, generate its mechanism of operation using the same underlying technology. Delivery of the laser energy and IPL energies through each specific applicator (either Laser or IPL) is monitored and controlled by the device's CPU. The user interface control panel provides the user with the optimal treatment settings taking into consideration the patient skin type and hair type (for hair removal treatments). Similarly to the cleared device, the Magma Spark Pro device user can decide on the optimal treatment settings and adjust these treatment settings through the control panel. Furthermore, Magma Spark Pro device, as the cleared Magma device, introduces similar safety features and comply with same relevant consensus standards. Minor differences are obtained in the hand pieces performance specifications (Max. fluence, tip size). These differences do not pose any new risks related to the device functionality and patient safety and do not alter the device safety and effectiveness.

Conclusions:

Based on the performance testing and comparison to predicate devices, the modified Magma Spark Pro device is found substantially equivalent to its cleared device for the mentioned indications for use and can be legally marketed in the USA.