DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 9, 2016

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

Re: K162781
Trade/Device Name: Magma Spark
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 29, 2016
Received: October 3, 2016

Dear Ahava Stein:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For 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: January 31, 2017
See PRA Statement below.

51O(k) Number *(if known)*

K162781

Device Name
Magma Spark

Indications for Use *(Describe)*

Magma Spark device is indicated for use in aesthetic and cosmetic applications in dermatology.

Magma Spark device has connection capability with the follo\ving available treatment hand-pieces (applicators), for multi-application treatment options. All hand-pieces are designed for aesthetic and cosmetic dem1atologic procedure applications. Magma Spark device \vith ALD or LLD diode laser applicators is indicated for hair removal, pennanent hair reduction* in skin types I-VI and for the treatment of pseudofolliculitis barbae (PFB).

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

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

IZJ 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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510(K) SUMMARY

MAGMA SPARK DEVICE

510(k) Number
K162781

Applicant Name:
Company Name: Formatk Systems Ltd
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Tel: +972-4-909-7440
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E-mail: ahava@asteinrac.com

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Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: September 29, 2016

Trade Name: Magma Spark

Classification Name: CFR Classification section 878.4810 (Product code GEX)

Classification: Class II Medical Device

Predicate Device:

Magma Spark device is substantially equivalent to the previously cleared, Magma device, also manufactured by Formatk Systems Ltd.

Device	Manufacturer	510(k) No.
Magma	Formatk Systems Ltd.	K153566

Device Description:

The Magma Spark device is a computerized multi-application platform intended for non-invasive aesthetic applications utilizing laser optical power.

Magma Spark is a relatively small tabletop device that provided with melanin meter and two diode laser applicators (ALD and LLD) at nominal 808 nm wavelength. The system platform includes AC/DC power supply unit, water based cooling system, CPU main card and user interface including an LCD display and touch screen module. The operator of Magma Spark chooses and monitors the mode and intensity of the treatment from a digital control panel on the front of the device.

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Input Current (A)	6.0 max
Platform dimensions (inch)	26.0''W x 21.7''D x 23.6''H
Platform weight (lb.)	50.7
ALD & LLD Diode laser wavelength (nm)	808
Maximal Fluence (J/cm^2):	
ALD	Up to 75
LLD	Up to 35

Intended Use/Indication for Use:

Magma Spark device is indicated for use in aesthetic and cosmetic applications in dermatology.

Magma Spark device has connection capability with the following available treatment hand-pieces (applicators), for multi-application treatment options. All hand-pieces are designed for aesthetic and cosmetic dermatologic procedure applications. Magma Spark device with ALD and LLD diode laser applicators iis indicated for hair removal, permanent hair reduction[1] in skin types I-VI and for the treatment of pseudofolliculitis barbae (PFB).

[1] Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after completions of treatment regime

Performance Standards:

Magma Spark complies with the following recognized consensus standards:

- AAMI/ANSI 60601-1 (2012), Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod).
- IEC 60601-1-2 (Edition 3.0, 2007), Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- IEC 60825-1 (Edition 2.0, 2007), Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)].
- IEC 60601-2-22 (Edition 3.0, 2007 & Edition 3.1 2012), Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment.

Non-Clinical (Bench) Performance Data:

The underlying technology and principle of operation of Magma Spark is essential the same as the predicate device. Therefore, results were gathered to support the safety of the modified device and thorough test of the software was executed. Comprehensive software-system test plan and results report covers the full system test of the Magma Spark. 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 components of modified Magma Spark device, similarly to predicate Magma device, generate its mechanism of operation using the same underlying technology. Delivery of the laser energy through each specific applicator (either ALD or LLD) 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). Since Magma Spark device is limited to operate with diode laser applicators only, the intended use of Magma Spark device is same as predicate Magma device in relation to the diode laser-relevant applications only. Using both modified and cleared devices the device user can decide on the optimal treatment settings and adjust these treatment settings through the control panel. Furthermore, Magma Spark device, as the cleared Magma device, introduces similar safety features and comply with same relevant consensus standards.

Conclusions:

Based on the comparison to predicate device, Magma Spark device is substantially equivalent to the predicate Magma device for the mentioned indication for use.