



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 6, 2016

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

Re: K153566

Trade/Device Name: Magma System
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: March 3, 2016
Received: March 7, 2016

Dear Ms. 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 yours,

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

Indications for Use

510(k) Number (if known)
K153566

Device Name
Magma System

Indications for Use (Describe)

The Magma System is indicated for use in aesthetic applications in dermatology.

The Magma System has connection capability with the following available treatment handpieces, for multi application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows:

1. The Magma System with ALD/LLD Laser Handpiece is indicated for hair removal, permanent hair reduction* in skin types I-VI and for the treatment of Pseudofolliculitis Barbae (PFB).

2. The Magma System with Nd:YAG Laser Handpiece (ND) with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:

- The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 - 4.0 mm. diameter) of the leg
- The 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.
- The non-ablative treatment of facial wrinkles

3. The Magma System with the Intense Pulsed Light (IPL) Handpieces (10 different Applicators) with a spectrum of 430-1100nm is indicated for:

HR*, F-HR*, B-HR* Applicators (650-1100nm):

- 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.

HR, F-HR, B-HR Applicators (590-1100nm):

- Removal of unwanted hair from skin types I-IV, and to effect stable long term, or permanent hair reduction* in skin types I-IV through selective targeting of melanin in hair follicles.

SR, F-SR, B-SR Applicators (530-1100nm):

- Benign epidermal lesions, including dyschromia, hyperpigmentation, ephelides (freckles)
- Cutaneous lesions, including 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.

F-AC Applicator (430-1100nm):

- 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)

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510(K) SUMMARY
MAGMA SYSTEM

510(k) Number K153566

Applicant Name:

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Date Prepared: April 06, 2016

Trade Name: Magma System

Classification Name: CFR Classification section 878.4810;
(Product codes GEX and ONF)

Classification: Class II Medical Device

Predicate Device:

The Magma System is substantially equivalent to the following predicate devices:

Manufacturer	Device	510(k) No.
Lumenis Ltd.	LightSheer Desire Light Laser System	K151947
Lumenis Ltd.	Lumenis M22 System	K142860

Device Description:

The Magma System is a computerized multi-application, multi-technology platform, intended for non-invasive aesthetic applications utilizing laser and Intense Pulsed Light (IPL) optical power.

The system platform includes AC/DC power supply unit, water based cooling system, CPU main card and user interface including a LCD display and touch screen module. Apart from the system platform the Magma System is provided with 13 applicators divided into three technology related sub-categories:

- ALD & LLD Diode laser (808nm) Applicators for hair removal treatments.
- Multi-spot Nd:YAG laser (1064nm) Applicator for coagulation and hemostasis of vascular lesions and soft tissue, hair removal treatments and non-ablative treatment of facial wrinkles.
- Ten Intense Pulsed Light (IPL) Applicators divided into four sub-categories:
 - HR*, F-HR* & B-HR* (650-1100nm) Applicators for hair removal treatments (skin types I-V).
 - HR, F-HR & B-HR (590-1100nm) Applicators for hair removal treatments (skin types I-IV).
 - SR, F-SR & B-SR (530-1100nm) Applicators for the treatment of pigmented and vascular lesions.
 - F-AC (430-1100nm) Applicator for acne treatments.

The operator chooses and monitors the mode and intensity of the treatment from a digital control panel on the front of the Magma System. The Magma System has two applicator ports; one for IPL based applicators and one for Laser applicators. The ports must be simultaneously connected with both laser and IPL applicators for the system to operate.

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Input Current	4.0-9.5 A
Platform dimensions	15.9''Wx21''Dx47.2''H
Platform weight	74.8 [lb]
ALD & LLD Diode laser wavelength	808nm
Nd:YAG laser wavelength	1064nm
IPL wavelength	430-1100nm
Maximal Fluence (J/cm ²):	
ALD	Up to 75
LLD	Up to 35

HR*, F-HR* & B-HR*	Up to 19
HR, F-HR & B-HR	Up to 20.2
SR, F-SR & B-SR	Up to 21.8
F-AC	Up to 21.8

Intended Use/Indication for Use:

The Magma System is indicated for use in surgical, aesthetic applications in the medical specialties of general and plastic surgery, and dermatology.

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

1. The Magma System with ALD/LLD Laser Handpiece is indicated for hair removal, permanent hair reduction* in skin types I-VI and for the treatment of Pseudofolliculitis Barbae (PFB).

2. The Magma System with Nd:YAG Laser Handpiece (ND) with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:
 - The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 - 4.0 mm. diameter) of the leg.
 - The 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.
 - The non-ablative treatment of facial wrinkles.

3. The Magma System with the Intense Pulsed Light (IPL) Handpieces (10 different Applicators) with a spectrum of 430-1100nm is indicated for:

HR*, F-HR*, B-HR* Applicators (650-1100nm):

- 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.

HR, F-HR, B-HR Applicators (590-1100nm):

- Removal of unwanted hair from skin types I-IV, and to effect stable long term, or permanent hair reduction* in skin types I-IV through selective targeting of melanin in hair follicles.

SR, F-SR, B-SR Applicators (530-1100nm):

- Benign epidermal lesions, including dyschromia, hyperpigmentation, ephelides (freckles)
- Cutaneous lesions, including 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.

F-AC Applicator (430-1100nm):

- 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:

The Magma System complies with the recognized consensus standards listed below:

- 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.
- IEC 60601-2-57 (Edition 2.0, 2011), Medical Electrical Equipment - Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use.

Non-Clinical Performance Data:

A set of performance tests was conducted on the Magma System to evaluate the system's safety and effectiveness and to verify that the Magma System adhere to all of the design requirement specifications.

The comprehensive software-system test plan and results report covers the full system test of the Magma System. 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.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the Magma System are substantially equivalent to the indications for use and technological characteristics of the suggested predicate devices – the LightSheer Desire Light Laser and the Lumenis M22 Systems.

The design and components in the Magma System, including the power inlet unit, CPU controller, laser and IPL units and display panel are similar to the design and components found in the predicate devices. The Magma System Applicators possess similar technological principals to the predicate devices Applicators of diode laser, Nd:YAG laser and IPL energy delivery systems. Although there are some noticeable differences between the Magma System and the predicate devices technological characteristics and system specifications the Magma System effectiveness and safety is maintained due to the similar functionality and mechanism of operation. Both devices present similar performance specifications (for the specified indication for use) and similar monitoring features in order to maintain the desired power output settings. The safety features and compliance with safety standards in the Magma System are similar to the safety features and compliance with safety standards found in the predicate devices. Patient contact materials are also similar. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the Magma System underwent performance testing, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, safety of laser products according to IEC 60825-1, basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment according to IEC 60601-2-22, and basic safety and essential performance of non-laser light source equipment intended for

therapeutic, diagnostic, monitoring and cosmetic/aesthetic use according to IEC 60601-2-57 and bench testing to evaluate the consistency of the laser and IPL power output. These performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Conclusions:

Consequently, it can be concluded that the Magma System is substantially equivalent to the LightSheer Desire Light Laser System, cleared under 510(k) K151947, and to the Lumenis M22 System, cleared under 510(k) K142860 and therefore, may be legally marketed in the USA.