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

April 15, 2016

Formatk Systems, Inc.
c/o Mr. Amit Goren
A. Stein-Regulatory Affairs Consulting
20 Hata'as Str., Suite 102
Kfar Saba 4442500 Israel

Re: K160195
Trade/Device Name: Forma System, Forma Light 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: ONF, PBX, ILY, GFE
Dated: January 17, 2016
Received: January 27, 2016

Dear Mr. 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. 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 Parts 801 and 809); 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" (21CFR 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

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.

510(k) Number *(if known)*
K160195

Device Name
Forma System
Forma Light System

Indications for Use *(Describe)*

The Forma System and Forma Light System** are indicated for use in aesthetic applications in dermatology.
The Forma System and Forma Light System** have 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 Forma System and Forma Light System** with the Intense Pulsed Light (IPL) Handpieces (10 different Applicators) with a spectrum of 430-1100nm are 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)
2) The Forma System with the ST Handpiece (Radio Frequency) is indicated for the treatment of relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
3) The Forma System with the PLG Handpiece (Microdermabrasion Applicator) is indicated for skin dermabrasion.
Notes:
* 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.
** The Forma Light System is a desktop model of the Forma System and is based on IPL technology only.

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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510(K) SUMMARY

FORMA SYSTEM &
FORMA LIGHT SYSTEM
510(k) Number K160195

Applicant Name:

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Date Prepared: April 14, 2016

Trade Name: Forma System
Forma Light System

Classification Name: Classification for the IPL Applicators:
CFR Classification section 878.4810;
(Product code ONF)
Classification for the ST Applicator:
CFR Classification section 878.4400;
(Product code PBX)
Classification for the PLG Applicator only:
CFR Classification section 878.4820;
(Product code GFE)

Classification: Class II Medical Device
Classification for the PLG Applicator only:
Class I 510(k) Exempt Medical Device

Predicate Device:

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

Manufacturer	Device	510(k) No.
Viora Ltd.	Viora Reaction System	K090221
Lumenis Ltd.	Lumenis M22 System	K142860

The Forma Light System is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) No.
Lumenis Ltd.	Lumenis M22 System	K142860

Device Description:

The Forma System is a multi-application, multi-technology platform, intended for non-invasive aesthetic applications utilizing Radio Frequency (RF) and Intense Pulsed Light (IPL) technologies.
The system platform includes an AC/DC power supply unit, an RF Generator, a CPU main card and user interface including a LCD display and touch screen module. In addition to the system platform, the Forma System is provided with 12 applicators according to the following technology related sub-categories:

- ST Applicator (Radiofrequency) for the treatment of relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- 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.
- PLG Applicator (Diamond ring) is indicated for skin dermabrasion.

The operator chooses and monitors the mode and intensity of the treatment from a digital control panel located on the front panel of the Forma System. The Forma System has three applicator ports; one for IPL based applicators, one for RF applicator and one

for the skin dermabrasion applicator. The ports must be simultaneously connected with all there applicators for the system to operate.

The Forma Light System is a model of the Forma System employing only IPL technology.

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Input Current (A)	3.2
Forma System dimensions (inch)	14.9''Wx19.6''Dx21.6''H
Forma Light System dimensions (inch)	13.8''Wx14.2''Dx13.8''H
Forma System weight (lb.)	26.4
Forma Light System weight (lb.)	19.8
IPL wavelength (nm)	430-1100
Maximal IPL Fluence (J/cm^2):	
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
Maximal RF Frequency (MHz)	2.0
Maximal RF output power (J/cm^3)	100

Intended Use/Indication for Use:

The Forma System and Forma Light System** are indicated for use in aesthetic applications in dermatology. The Forma System and Forma Light System** have 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 Forma System and Forma Light 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)

2) The Forma System with the ST Handpiece (Radio Frequency) is indicated for the treatment of relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.

3) The Forma System with the PLG Handpiece (Microdermabrasion Applicator) is indicated for skin dermabrasion.

Notes
* 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.
** The Forma Light System is a desktop model of the Forma System, employing only IPL technology.

Performance Standards:

The Forma System and the Forma Light System comply with the recognized consensus standards listed below:
<u>Forma System and Forma Light System:</u>

- 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 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.

Forma System Only:

- IEC 60601-2-2 (Edition 5.0, 2009), Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgery Equipment And High Frequency Surgical Accessories.

Non-Clinical Performance Data:

A set of performance tests was conducted on the Forma System and Forma Light System to evaluate the systems' safety and effectiveness and to verify that the Forma System and Forma Light 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 Forma System and Forma Light 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.
The ST Applicator (Forma System only) was further tested in a set of bench tests to evaluate the device RF output power accuracy compared with the device design requirements and with the predicate device performance specifications. The bench tests also evaluated the tissue temperature profile following a treatment with the Forma System ST Applicator. The test results demonstrate that the ST Applicator performs according to the design requirement specifications and that it is substantially equivalent to the predicate device. The temperature profile testing showed a safe and effective tissue heating profile achieved with the Forma System ST Applicator.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the Forma System are substantially equivalent to the indications for use and technological characteristics of the predicate devices; the Viora Reaction and the Lumenis M22 Systems.

The design and components in the Forma System, including the power inlet unit, CPU controller, RF Generator, IPL unit and display panel are similar to the design and components found in the predicate devices. The Forma System Applicators possess similar technological principals to the predicate devices applicators also employing RF and IPL energy delivery systems. Although there are some minor differences between the Forma System and the predicate devices technological characteristics the Forma 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 Forma 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 Forma 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, 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, basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories according to IEC 60601-2-2, and bench testing to evaluate the consistency and accuracy of the RF and IPL power outputs. 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.

For the same reasons, the Forma Light System, consisting of the same IPL technological features as in the Forma System, is also substantially equivalent to the predicate device; the Lumenis M22 System.

Conclusions:

Consequently, it can be concluded that:

- The Forma System is substantially equivalent to the Viora Reaction, cleared under 510(k) K090221, and to the Lumenis M22 System, cleared under 510(k) K142860.
- The Forma Light System is substantially equivalent to the Lumenis M22 System, cleared under 510(k) K142860.

Therefore, both the Forma System and the Forma Light System may be legally marketed in the USA.