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 18, 2016

Viora Ltd.
Stella Perry
Regulatory Affairs Manager
6 Hagavish Street
Netanya, 4250706 IL

Re: K162363
Trade/Device Name: V30 System, V-form Handpiece Bc Medium Applicator
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, PBX, ISA
Dated: October 26, 2016
Received: October 31, 2016

Dear Stella Perry:

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.

510(k) Number *(if known)*

K162363

Device Name
V30 system
V- Form Handpiece BC Medium applicator

Indications for Use *(Describe)*

The Viora V30 system is intended for dermatological procedures.
The V-ST Handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The V-IPL Handpiece with wavelengths 415-l200nm (with 5 different filters) is
indicated for the treatment of:
• Moderate inflammatory acne vulgaris.
• Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
• Cutaneous lesions including warts, scars and striae.
• Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and venous malformations.
• Removal unwanted hair. It is also intended for permanent reduction in unwanted hair. 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 regimen.

The V-Nd:YAG Handpiece with wavelength 1064 nm comes with 4 different applicator spot diameters: 2x4, 3.5, 5.5 and 9.5 mm.
The three smaller spot sizes (2x4, 3.5, 5.5 mm) are intended for:
• Benign vascular lesions such as, but not limited to treatment of: port wine stains, hemangiomas, Warts, superficial and deep telangiectasias (venulectasias), reticular veins (0.1-4.0 mm dia.) of the leg, rosacea, venus lake, leg veins, spider veins, poikiloderma of civatte and angiomas.
• Benign cutaneous lesions, such as, but not limited to: warts, scars, striae and psoriasis.
• Benign pigmented lesions such as, but not limited to: lentigos (age spots), solar lentigos (sun spots), cafe-aulait macules, seborrheic keratosis, nevi and nevus of Ota, chloasma, verrucae, skin tags and keratosis.
• Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
• The non-ablative treatment of facial wrinkles, such as, but not limited to: periocular wrinkles and perioral wrinkles.
The Handpiece with a spot size of 9.5 mm is also intended for treatment of:
• Laser skin resurfacing procedures for the treatment of: acne scars and wrinkles. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
• The Handpiece with a spot size of 9.5 mm is also is intended for removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. 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 regimen and treatment of pseudofolliculitis barbae (PFB).

The V-Form Handpiece (with BC Small, Medium and Large applicators) is indicated for delivering non thermal RF combined with massage:
• relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and
• temporary reduction in the appearance of cellulite.

The Viora V20 and V10 systems with V-Form Handpiece (with BC Small, Medium and Large applicators) are indicated for delivering non thermal RF combined with massage:
• relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and
• temporary reduction in the appearance of cellulite.

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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Viora Ltd. 6 Hagavish Street Netanya, Israel 4250706 Israel
Contact Person:	Stella Raizelman Perry RA Manager Email: Stella@vioramed.com Phone Number: +972 9955 1344 Fax Number: +972 9955 1345
Establishment Registration Number:	3005695724
Date Prepared:	August 17, 2016
Device Trade Name(s):	**V30 system, V-Form Handpiece BC Medium Applicator**
Device Common Name:	Multi application RF, IPL and Laser device, RF based applicator
Classification:	**Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology and Electrosurgical cutting and coagulation device and accessories. **Product code:** GEX, PBX, ISA **Regulation No:** 21 CFR878.4810, 21CFR878.4400 **Class:** II **Panel:** General and plastic surgery devices
Predicate Device(s):	Viora V-total system (K133837) Viora V20 system (K152611) Viora V10 system (K150035)

Device description

The Viora ***V30 system*** is a multi-application, multi-technology platform device intended for use in dermatologic procedures.

The main console unit incorporates a touch-screen control panel, power supply modules, cooling system, switching module and service panel. The system includes four Handpieces and footswitch. The ***V30 system*** is cooled by deionized water.

The Viora ***V30 system*** is available with four treatment Handpieces:

- **V-ST Handpiece** - Bi-polar radiofrequency (RF) Handpiece
- **V-IPL Handpiece** - Intense pulsed light (IPL) Handpiece
- **V-ND:YAG Handpiece** - Long pulse neodymium-doped yttrium aluminum laser Handpiece
- **V- Form Handpiece** - with BC Small, BC Medium and BC Large applicators

The V- Form BC Medium applicator is Bi-polar radiofrequency (RF) applicator.

The applicator is supported by Viora's V10, V20 and V30 systems.

Intended use and indication for use statement

The Viora ***V30 system*** is intended for dermatological procedures.

The **V-ST Handpiece** is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The **V-IPL Handpiece** with wavelengths 415-l200nm (with **5** different filters) is indicated for the treatment of:

- Moderate inflammatory acne vulgaris.
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- Cutaneous lesions including warts, scars and striae.

- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and venous malformations.
- Removal unwanted hair. It is also intended for permanent reduction in unwanted hair. 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 regimen.

The **V-Nd:YAG Handpiece** with wavelength 1064 nm comes with 4 different applicator spot diameters: 2x4, 3.5, 5.5 and 9.5 mm.
The three smaller spot sizes (2x4, 3.5, 5.5 mm) are intended for:

- Benign vascular lesions such as, but not limited to treatment of: port wine stains, hemangiomas, Warts, superficial and deep telangiectasias (venulectasias), reticular veins (0.1-4.0 mm dia.) of the leg, rosacea, venus lake, leg veins, spider veins, poikiloderma of civatte and angiomas.
- Benign cutaneous lesions, such as, but not limited to: warts, scars, striae and psoriasis.
- Benign pigmented lesions such as, but not limited to: lentigos (age spots), solar lentigos (sun spots), cafe-aulait macules, seborrheic keratosis, nevi and nevus of Ota, chloasma, verrucae, skin tags and keratosis.
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to: periocular wrinkles and perioral wrinkles.

The Handpiece with a spot size of 9.5 mm is also intended for treatment of:

- Laser skin resurfacing procedures for the treatment of: acne scars and wrinkles. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

- The Handpiece with a spot size of 9.5 mm is also is intended for removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. 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 regimen and treatment of pseudofolliculitis barbae (PFB).

The ***V-Form Handpiece (with BC Small, Medium and Large applicators)*** is indicated for delivering non thermal RF combined with massage:

- relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and
- temporary reduction in the appearance of cellulite.

The Viora ***V20 and V10 systems with V-Form Handpiece (*****with BC Small, Medium and Large applicators)** are indicated for delivering non thermal RF combined with massage:

- relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and
- temporary reduction in the appearance of cellulite.

Predicade Devices

The predicate devices for Viora V30 system with V-Form Handpiece for this Premarket Notification are the following:

Device Name	**510k No.**	**Date of Clearance**
Viora V-total (V30 system)	K133837	April 9, 2014
Viora V20 system	K152611	February 19, 2016

The Predicate devices for V- Form BC Medium applicator are:

Device name	**510k No.**	**Date of Clearance**
Viora V20 system	K152611	February 19, 2016
Viora V10 system	K150035	May 1, 2015

Substantial Equivalence to Predicate Device

The ***V30 system with the V- Form Handpiece*** and its predicate devices have the same intended use and the same indications for use. The proposed **V-ST**, V-**IPL** and V-**Nd: YAG** Handpieces have the same technological characteristics and the same performance characteristics as the cleared Viora **V-total ST**, **IPL** and **Nd:Yag Laser** Handpieces (K133837). Therefore, no new safety or efficacy issues can be raised.
The Viora **V30 V-Form** Handpiece is exactly the same as the cleared Viora **V20 V-Form** Handpiece (K152611)). The V-Form Handpiece has the same technological characteristics and the same performance as the predicate device. Therefore, no new safety or efficacy issues can be raised.
Any differences in the software and in the system design do not raise any new issues of safety and effectiveness, as was verified by performance testing.
Therefore, the ***V30 system with the V- Form Handpiece*** is substantially equivalent to its predicate devices.

The ***V-Form Handpiece BC Medium Applicator*** and the Viora V- Form BC Large Applicator (K152611, K150035) have identical intended use and similar technological features. Any differences in the V-Form Handpiece design do not raise any new questions of safety and effectiveness, as verified by performance testing.Therefore, the ***V-Form Handpiece BC Medium Applicator*** is substantially equivalent to its predicate devices.

Performance standards

The ***V30 system*** complies with:

- **IEC 60601-1**: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
- **IEC 60601-1-2**: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.

- **IEC 60601-2-2:** Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories.
- **IEC 60601-2-57:** Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use.
- **IEC 60601-2-22:** Particular Requirements For Basic Safety And Essential Performance of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment.
- **IEC 60825-1:** Safety of Laser Products - Part 1: Equipment Classification, And Requirements

The Viora ***V20 and V10 systems with V-Form Handpiece BC Medium applicator*** comply with:

- **IEC 60601-1:** Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
- **IEC 60601-1-2**: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.
- **IEC 60601-2-2**: Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories.

Performance Bench Tests

Bench testing demonstrated that the ***V30 system (with the V- Form Handpiece) and the V-Form Handpice BC Medium applicator*** are as safe and effective as the cleared predicate devices.

Pre-Clinical and clinical study

Since the technological parameters of the Viora ***V30 system with the V- Form Handpiece*** and of the ***V-Form Handpice BC Medium applicator*** are well within the parameters of the previously cleared V-total, V20 and V10 systems, Viora believes that animal and clinical studies are not required to determine the safety and efficacy of the ***V30 system with the V- Form Handpiece*** and of the ***V-Form Handpice BC Medium applicator.***

Conclusion

Based on the technological characteristics of the devices and the intended use, Viora believes that the ***V30 system with the V- Form Handpiece*** and the ***V-Form Handpice BC Medium applicator*** are substantially equivalent to the predicate devices. The differences do not raise any new issues of safety or effectiveness.