



Food and Drug Administration
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February 19, 2016

Viora Ltd.
Omri Kesler
Chief Operating Officer
3 Maskit Street
Herzliya, ISREAL 4673303

Re: K152611
Trade/Device Name: V20 System
Regulation Number: 21 CFR 878.4810
Regulation Name: General and Plastic Surgery Devices
Regulatory Class: Class II
Product Code: GEX, PBX, ISA
Dated: January 18, 2016
Received: January 21, 2016

Dear Omri Kesler,

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 -S

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)

K152611

Device Name

V20 system

Indications for Use (Describe)

The Viora V20 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 415-1200nm (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-Form Handpiece (with BC and FC 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.

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.

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Establishment Registration Number: 3005695724

Date Prepared: September 09, 2015

Device Trade Name(s): **V20 system**

Device Common Name: Multi application RF and IPL device

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 V20 system (K142093)
Viora V10 system (K150035)



Device description

The Viora **V20 system** is a RF and IPL multi application platform with three available treatment Handpieces:

V-ST Handpiece - Bi polar radiofrequency (RF) Handpieces

V-IPL Handpiece - Intense Pulsed Light (IPL) Handpiece

V- Form Handpiece (with BC and FC applicators) – mechanical vacuum massage and Bi-polar radiofrequency (RF) Handpiece.

The Main Unit (console) provides the operational and safety function of the system. The operator can modify the treatment parameters to achieve specific tissue effects depending on individual patient's skin condition and anatomical structure. The Foot Switch is used for system activation.

Intended use and indication for use statement

The Viora V20 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 415-1200nm (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-Form Handpiece (with BC and FC 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.

Predicade Devices

Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No.	Date of Clearance
Viora V20 system	K142093	November 14, 2014
Viora V10 system	K150035	May 1, 2015

Substantial Equivalence to Predicate Device

The *V20 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** and **V-IPL** Handpieces have the same technological characteristics and the same performance characteristics as the cleared Viora **V20 V-ST** and **V-IPL** Handpieces (K142093). Therefore, no new safety or efficacy issues can be raised.

The Viora **V20 V-Form** Handpiece is exactly the same as the cleared Viora **V10 V-Form** Handpiece (K150035). 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 *V20 system with the V- Form Handpiece* is substantially equivalent to its predicate devices.



Performance standards

The *V20 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.

Performance Bench Tests

Bench testing demonstrated that the *V20 system (with the V- Form Handpiece)* is as safe and effective as the cleared predicate devices.

Pre-Clinical and clinical study

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

Conclusion

Based on the technological characteristics of the devices and the intended use, Viora believes that the *V20 system with the V- Form Handpiece* and the predicate devices are substantially equivalent. The differences do not raise any new issues of safety or effectiveness.