May 21, 2020

Viora Ltd.
Ms. Simona Krant, QA/RA Director
6 Hagavish Street
Netanya, 4250706
Israel

Re: K200468
Trade/Device Name: V30 system, V20 system, V10 system, V-FC Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulatory Class: Class II
Product Code: PBX, GEX
Dated: April 07, 2020
Received: April 15, 2020

Dear Ms. Krant:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200468

Device Name
V-FC Handpiece compatible with V30, V20, V10 Systems

Indications for Use *(Describe)*

The Viora V10 system is intended for dermatological procedures.
The V10 system with V-FC Handpiece 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 system is intended for dermatological procedures.
The V20 system with V-FC Handpiece 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 V30 system is intended for dermatological procedures.
The V30 system with V-FC Handpiece 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) K200468**

## 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.<br>6 Hagavish Street<br>Netanya, Israel 4250706<br>Israel |
| **Contact Person:** | Ms. Simona F. Krant<br>QA/RA Director<br>Email: Simona@Vioramed.com<br>Phone Number: +972 9955 1344<br>Fax Number: +972 9955 1345 |
| **Establishment Registration Number:** | 3005695724 |
| **Date Prepared**: | May 21, 2020 |
| **Device Trade Name(s):** | **V-FC Handpiece compatible with V30, V20, V10 Systems** |
| **Device Common Name:** | Bipolar 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.<br>**Product code:** GEX, PBX, ISA (for V30 system)<br>GEX, PBX, ISA (for V20 system)<br>PBX, ISA (for V10 system)<br>**Regulation No:** 21CFR878.4810, 21CFR878.4400<br>**Class:** II<br>**Panel:** General and plastic surgery devices |
| **Predicate Device(s):** | Viora V30 system with V-FORM handpiece (K162363)<br>Viora V20 system with V-FORM handpiece (K152611)<br>Viora V10 system with V-FORM handpiece (K150035) |

**Device description**

| System | Description | Applications | 510(k) Clearance |
|---|---|---|---|
| ***V30*** | 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.<br>Cooled by deionized water | Nd:YAG (V30)<br>For V20 & V30:<br>V-ST, V-IPL, V- and V-FORM (with BC Small, Medium and Large applicators) | November 18, 2016 (K162363). |
| **V20** | | | February 19, 2016 (K152611)<br>&<br>November 18, 2016 (K162363). |
| **V10** | based on the well-established bipolar radiofrequency (RF) technology used for heating of soft tissues. The main console unit incorporates a touch-screen control panel, power supply modules, RF generator and service panel. | V-ST and V-FORM (with BC Small and Large applicators) | May 1, 2015 (K150035)<br>&<br>November 18, 2016 (K162363). |

The ***V-FC Handpiece*** is supported by ***Viora's V10, V20 and V30*** systems.

**Indication for Use for V-FC Handpiece compatible with V30, V20, V10 Systems**

The Viora V10 system is intended for dermatological procedures.
The V10 system with V-FC Handpiece 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 system is intended for dermatological procedures.
The V20 system with V-FC Handpiece 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 V30 system is intended for dermatological procedures.
The V30 system with V-FC Handpiece 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.

**Predicate Devices**

The predicate device to Viora systems V10, V20 and V30 are the cleared ***V10, V20 and V30*** **systems** themselves (please refer to the table below).

| Device name | 510k No. | Date of Clearance | Compatible Predicate Handpiece |
|---|---|---|---|
| Viora V10 | K150035 | Cleared on May 1, 2015 | V-FORM |
| Viora V20 | K152611 | Cleared on February 19, 2016 | V-FORM |
| Viora V30 | K162363 | Cleared on November 18, 2016 | V-FORM |

The predicate device to ***V-FC Handpiece compatible with V30, V20, V10 Systems*** is V10, V20, V30 systems with V-FORM handpiece,(Viora Ltd.) including BC large, small and medium applicators.

**Substantial Equivalence to Predicate Device**

| Comparison Parameter | Subject Device: V10,V20 and V30 systems with V-FC Handpiece | Predicate Device: V10,V20 and V30 systems with V-FORM handpiece | Characteristic Comparison (same/different) |
|---|---|---|---|
| **Device Class** | Class II | Class II | Same |
| **Classification Panel** | General and Plastic Surgery devices | General and Plastic Surgery devices | Same |
| **Product code** | 21CFR878.4400 (V10,V20 & V30)<br>21CFR878.4810 (V20 & V30) | 21CFR878.4400 (V10,V20 & V30)<br>21CFR878.4810 (V20 & V30) | Same |
| **Regulation number** | PBX, ISA (V10,V20 & V30)<br>GEX (V20 & V30) | PBX, ISA (V10,V20 & V30)<br>GEX (V20 & V30) | Same |
| **Regulation description** | Electrosurgical cutting and coagulation device and accessories. | Electrosurgical cutting and coagulation device and accessories. | Same |
| **Device main components** | Cleared **V10,V20 and V30 systems** with: V-FC Handpiece, connector, cable handpiece. | Bipolar RF Applicator, connector, cable handpiece | Same |
| **Supported technologies** | The cleared **V10,V20 and V30 systems** include RF (V10,V20 & V30)<br>IPL ( V20 & V30) and Laser(V30) | The cleared **V10,V20 and V30 systems** include RF (V10,V20 & V30)<br>IPL ( V20 & V30) and Laser(V30) | Same |
| **Intended use and indication for use** | The V10,V20 and V30 systems with V-FC Handpiece are intended 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 V10,V20 and V30 systems with V-FORM handpiece are intended 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 | Same |

| Comparison Parameter | Subject Device:<br>V10,V20 and V30 systems with V-FC Handpiece | Predicate Device:<br>V10,V20 and V30 systems with V-FORM handpiece | Characteristic Comparison (same/different) |
|---|---|---|---|
| **System user interface** | V10 & V20: 8.1-inch touch screen<br>V30:10.4-inch touch screen | V10 & V20: 8.1-inch touch screen<br>V30:10.4-inch touch screen | Same |
| **Handpiece dimensions:** | 17x25.6 cm | 23x23 cm | Different but equivalent |
| **Handpiece weight** | 0.625 kg | 0.75 kg | Different but equivalent |
| **Electrical requirements:** | 100-240 V~ 10A 50/60 Hz (V10,V20 & V30)<br>100-120 V~ 10A 50/60 Hz (V20 & V30)<br>Single Phase | 100-240 V~ 10A 50/60 Hz (V10,V20 & V30)<br>100-120 V~ 10A 50/60 Hz (V20 & V30)<br>Single Phase | Same |
| **Maximum vacuum level** | Up to 450 mbar | Up to 500 mbar | Different but equivalent |
| **Software** | The V10,V20 and V30 systems software supports the V-FC Handpieces.<br>The software was verified and validated according to the FDA guidance. | According to 510(k) summaries<br>V10: K150035<br>V20: K152611<br>V30: K162363. | Same |

**Summary of technologic characteristics**

The Viora ***V-FC Handpiece compatible with V30, V20, V10 Systems*** and the predicate device have similar intended use and indication for use, identical technological features and identical performance characteristics. The ***V10, V20 and V30*** console has similar technological characteristics as the predicate device, performance and software validation data demonstrate that the differences between the ***V-FC Handpiece compatible with V30, V20, V10 Systems*** support and the predicate do not raise any new questions of safety and effectiveness.

The ***V-FC Handpiece*** and the predicate device have similar intended use and similar technological features. Any differences in the ***V-FC Handpiece*** design do not raise any new questions of safety and effectiveness, as was verified by performance testing.

In conclusion, the ***V-FC Handpiece compatible with V30, V20, V10 Systems*** is substantially equivalent to its predicate device. Therefore, we concluded that the V-FORM for the ***V-FC handpiece*** appears to be an adequate predicate for this submission.

**Performance standards**

The ***V-FC Handpiece compatible with V30, V20, V10 Systems*** comply with the following performance standards:

| System Relevance | Standard Number | Part Title |
|---|---|---|
| V10,V20,V30 | IEC 60601-1:2012 | Medical Electrical Equipment Part 1:General Requirements for Basic Safety and Essential Performance |
| V10,V20,V30 | IEC 60601-1-2: 2014 | Medical Electrical Equipment Part 1-2:General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. |
| V20,V30 | IEC 60601-2-57:2011 | Particular Requirements for The Basic Safety and Essential Performance of Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use. |
| V20,V30 | IEC 60601-2-22:2007 | Particular Requirements for Basic Safety And Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment. |
| V20,V30 | IEC 60825-1:2014 | Safety of Laser Products Part 1: Equipment Classification, And Requirements |

**Electrical Safety and Electromagnetic Compatibility**:

The ***V-FC Handpiece compatible with V30, V20, V10 Systems*** was determined to be in conformance with applicable IEC standards as described in the above table.

**Performance Bench Tests**

Dedicated tests were performed during three days to assess the V-FC handpiece capability to safely maintain superficial skin therapeutic temperature between 39-42℃ during theopoetic 14 minutes of treatment.

The integrated IR thermometer indicating the skin temperature over the system GUI screen and LED's temperature indication on the handpiece provided the practitioner ongoing monitoring. In cases of temperature decreasing below 39℃ or increasing above 42℃ the practitioner investigator was able to react immediately to increase /decrease the RF power.

In addition to increase the safety profile, the system software is designed in such way that once the handpiece IR sensor detects body temperature above 47℃, the system stops delivery of RF energy. Since reaching body temperature above 43℃ was painful these was not tested on the participants. However, previous ex-vivo tests on the chicken breast did tested temperature above 47℃ (CRF-2). In this test the system stopped RF energy delver once detected 47℃ and the meat returned to lower temperature about 30 sec post the break.

According to the collected data from these tests it can be concluded that the V-FC handpiece can be easily operated to ensure therapeutic body temperature between 39-42℃, while treating in operating room temperature between 10° C to 30° C and according the device specifications and are as safe and effective as the cleared predicate devices.

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**Biocompatibility**:

The materials and biocompatibility characteristics of ***Viora V10, V20, V30 systems***, except of the material of the new Handpiece V-FC remains the same as approved (K150035, K152611, and K162363 respectively).

Thus, all components that come into contact with the skin (tip, electrodes) are bio-compatible and meet the requirement of the ISO 10993-1.

Additional biological evaluation for the V-FC Handpiece is considered to have meet the requirements for a surface device with limited to transient contact and can be considered safe and suitable for its intended use.

**Software**:

Software verification and validation testing was conducted, and results demonstrated that testing results were found acceptable for software release.

All performance testing demonstrated that the ***Viora V10, V20, V30 system*** with ***V-FC Handpiece*** performs according to specifications and functions as intended.

**Clinical Study**

Since the technological parameters of the ***Viora V10, V20, V30 system*** with ***V-FC Handpiece*** is well within the parameters of the previously cleared V30, V20 and V10 systems, Viora believes that pre-clinical and clinical studies are not required to determine the safety and efficacy of the ***Viora V10, V20, V30 system*** with ***V-FC Handpiece.***

**Conclusion**

The non-clinical data further support the safety of the device, and software verification and validation testing demonstrate that the ***Viora V10, V20, V30 system*** with ***V-FC Handpiece*** is expected to perform as intended in the specified use conditions. Based on the technological characteristics of the devices and the intended use, Viora believes that the ***Viora V10, V20, V30 system*** with ***V-FC Handpiece*** is substantially equivalent to the predicate devices. The differences do not raise any new issues of safety or effectiveness.