July 15, 2020

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

Re: K201064
Trade/Device Name: V30 System, V20 System, V10 System, V-FR Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX, ISA, GEX, GEI
Dated: March 31, 2020
Received: April 21, 2020

Dear Simona 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)*
K201064

Device Name
V30, V20, V10 systems
V-FR handpiece

Indications for Use *(Describe)*
The Viora V10 system is intended for dermatological procedures.
The V10 system with V-FR is indicated for dermatological procedures requiring ablation and resurfacing of the skin.

The Viora V20 system is intended for dermatological procedures.
The V20 system with V-FR is indicated for dermatological procedures requiring ablation and resurfacing of the skin.

The Viora V30 system is intended for dermatological procedures.
The V30 system with V-FR is indicated for dermatological procedures requiring ablation and resurfacing of the skin.

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 **Device**

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:	Ms. Simona F. Krant QA/RA Director Email: Simona@Vioramed.com Phone Number: +972 9955 1344 Fax Number: +972 9955 1345
Establishment Registration Number:	3005695724
Date Prepared:	July 14, 2020
Device Trade Name(s):	**V-FR Handpiece compatible with V30, V20, V10 Systems**
Device Common Name:	Multi-application RF, IPL and Laser device, RF based applicator
Classification:	**Name:** Electrosurgical cutting and coagulation device and accessories and Laser surgical instrument for use in general and plastic surgery and in dermatology. **Product code:** PBX, ISA, GEI, GEX (for V30 system) PBX, ISA GEI, GEX (for V20 system) PBX, ISA, GEI (for V10 system) **Regulation No:** 21CFR878.4400, 21CFR878.4810 **Class:** II **Panel:** General and plastic surgery devices
Predicate Device(s):	Viora V30 system (K162363) Viora V20 system (K152611) Viora V10 system (K150035) Syneron Medical Matrix RF Applicator (K090025)

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. Cooled by deionized water	Nd:YAG (V30) For V20 & V30: V-ST, V-IPL, V- and V-FORM (with BC Small, Medium and Large applicators)	November 18, 2016 (K162363).
V20			February 19, 2016 (K152611) & 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) & November 18, 2016 (K162363).

The ***V-FR Handpiece*** is fractional Bi-polar radiofrequency (RF) Handpiece. The 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-FR is indicated for dermatological procedures requiring ablation and resurfacing of the skin.

The Viora V20 system is intended for dermatological procedures.
The V20 system with V-FR is indicated for dermatological procedures requiring ablation and resurfacing of the skin.

The Viora V30 system is intended for dermatological procedures.
The V30 system with V-FR is indicated for dermatological procedures requiring ablation and resurfacing of the skin.

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) and the ***V-FR handpiece*** is ***Syneron Medical Matrix RF Applicator*** that was cleared for marketing on January 8, 2010 (**K090025**).

Device name	510k No.	Date of Clearance
Viora V10	K150035	Cleared on May 1, 2015
Viora V20	K152611	Cleared on February 19, 2016
Viora V30	K162363	Cleared on November 18, 2016
Syneron Medical Matrix RF Applicator	K090025	Cleared on January 8, 2010

Substantial Equivalence to Predicate Device

Comparison Parameter	Subject Device: V10,V20 and V30 systems with V-FR Handpiece	Predicate Device: Matrix RF Applicator Syneron Medical Ltd.	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	PBX, ISA , GEI (V10,V20 & V30) GEX (V20 & V30)	GEI	Same for FR Technology
Regulation number	21CFR878.4400 (V10,V20 & V30) 21CFR878.4810 (V20 & V30)	21CFR878.4400	Same
Regulation description	Laser Surgical Instrument for Use in General and plastic surgery and in dermatology. 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.	• Matrix RF Applicator, connector, cable handpiece • Disposable, sterilized treatment tips • Disposable, sterilized test tips	Same
Supported technologies	The cleared V10,V20 and V30 systems -with V-FR Handpiece, are supported with RF technology	Matrix RF Applicator is supported with RF technology	Same
Intended use and indication for use	The V10,V20 and V30 systems with V-FC Handpiece are intended for dermatological procedures requiring ablation and resurfacing of the skin circulation and temporary reduction in the appearance of cellulite.	The Matrix RF Applicator is intended for use in dermatological procedures, requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles, circulation and temporary reduction in the appearance of cellulite	Similar, V-FR does not treat facial wrinkles
System user interface	V10 & V20: 8.1-inch touch screen V30:10.4-inch touch screen	High-resolution color, 15" LCD V30:10.4-inch touch screen	Different but equivalent
Handpiece dimensions:	18x16cm	15x16cm	Different but equivalent
Handpiece weight	0.4 kg	0.5 kg	Different but equivalent
Electrical requirements:	100-240 V~ 10A 50/60 Hz (V10,V20 & V30) 100-120 V~ 10A 50/60 Hz (V20 & V30) Single Phase	100 – 230 VAC ±10%; 3A; 50/60Hz Single Phase	Same
Software	The V10,V20 and V30 systems software supports the V-FR Handpieces. The software was verified and validated according to the FDA guidance.	According to 510(k) summary K090025, the software was verified and validated according to the FDA guidance	Same

Summary of technologic characteristics

The technological differences between Viora ***V-FR Handpiece compatible with V30, V20, V10 Systems*** and the predicate device ***Matrix RF Applicator Syneron Medical Ltd.*** do not raise any new questions of safety or effectiveness.

The non-clinical testing, software verification and validation testing and animal study were performed to evaluate the performance of ***V-FR Handpiece compatible with V30, V20, V10 Systems.***

Based on comparison of the technological characteristics of the devices and results of the performance testing, ***V-FR Handpiece compatible with V30, V20, V10 Systems*** is substantially equivalent to the predicate device ***Matrix RF Applicator Syneron Medical Ltd.*** for requested intended use."

In conclusion, the ***V-FC Handpiece compatible with V30, V20, V10 Systems*** is substantially equivalent to its predicate device. Therefore, we concluded that the ***Matrix RF Applicator Syneron Medical Ltd.*** for the ***V-FR Handpiece compatible with V30, V20, V10 Systems*** 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-FR 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:

Bench testing demonstrated that the ***V-FR Handpiece compatible with V30, V20, V10 Systems*** performs per its device specifications and are as safe and effective as the cleared predicate devices.

Biocompatibility:

The materials and biocompatibility characteristics of ***Viora V10, V20, V30 systems*** remains the same as approved (K150035, K152611, and K162363 respectively). Addition biocompatibility tests were performed according to ISO 10993-1 for the ***V-FR tip*** - Cytotoxicity test, Irritation test, Sensitization test. Results showed that the ***V-FR tip*** materials meet the requirement of the ISO 10993-1 for surface device that contacts breached or compromised surface in limited contact duration with the skin.

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 ***V-FR Handpiece compatible with V30, V20, V10 Systems*** performs according to specifications and functions as intended.

Pre-Clinical (Animal) study

The Animal prospective study was conducted to evaluate the safety and effectiveness of the ***V-FR Handpiece compatible with V30, V20, V10 Systems*** for dermatological procedures requiring ablation and resurfacing of the skin.

The study was comprised female domestic pigs (*Sus scrofa domestica*), each subjected to multiple topical exposures of fractional radio frequency pulses *via* the ***V-FR handpiece*** connected to ***Viora V10, V20, V30 systems*** by which different settings, such as depth of penetration, pulse energy and duration.

Animals were evaluated macroscopically for local reaction at Day 0, Day 3, Day 7 and at study's termination 14 days post Activation. Skin biopsies were harvested on the same days and evaluated for depth/width of the ablated tissue and coagulative necrosis.

Action of the V-FR handpiece (i.e., a fractional radiofrequency system) was confirmed in this study to consist of coagulation and ablation of the epidermis and the superficial dermis. **Histopathological evaluation** of the tissue samples indicated that, there was a well circumscribed condensation of the epidermis (i.e., coagulation necrosis), strictly limited only to small “islets” of the treated tissue, leaving intact skin in-between these islets. The healing was confirmed to be initiated from these intact skin areas resulting in lack of any evidence for adjacent tissue complications (i.e., inflammation, thrombosis). Histopathological evaluation of the activation sites indicated a clear and consistent time-related progressive change in the morphologic aspect of the sites, generally reflecting trend for healing without associated adverse reaction. This trend was evident in all combinations of type of programs / energy settings / pulse durations. Ablations were mainly restricting pod to the high-power settings (i.e. 8 & 10J) and coagulated necrosis was noted in all type of setting combinations on the day of application.

The results of the animal study demonstrated the favorable safety and effectiveness profile for the ***Viora V10, V20, V30 systems*** for the indicated use for ablation and resurfacing of the skin with no device related serious adverse events.

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

Conclusion:

The technological differences between subject and predicate devices do not raise any new questions of safety or effectiveness. The non-clinical testing, software verification and validation testing and animal study were performed to evaluate the performance of Viora V10, V20, V30 system with V-FR Handpiece.

Based on comparison of the technological characteristics of the devices and results of the performance testing, Viora V10, V20, V30 system with V-FR Handpiece are substantially equivalent to the predicate devices for requested intended use.