DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2014

Viora Ltd.
% Yoram Levy
Qsite
31 Haavoda Street
Binyamina, Israel 30500

Re: K141904
Trade/Device Name: V-Touch
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 1, 2014
Received: October 3, 2014

Dear Mr. Levy:

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" (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,

David Krause -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

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)*
K141904

Device Name
V-Touch

Indications for Use *(Describe)*
The V-Touch is intended for dermatological procedures.

The ST applicator is indicated for the treatment of relief of minor muscle aches and pain, relief of muscle spasm and temporary improvement of local blood circulation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY

V-Touch

510(k) Number K141904

Applicant's Name: Viora Ltd.
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Contact Person: Yoram Levy, Qsite
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Binyamina, Israel 30500
Tel +(972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***V-Touch***

Common Name: Multi application RF Device

Preparation Date: July 08, 2014

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

Viora's ***V-Touch*** system combines **CORE™** (**C**hanneling **O**ptimized **R**F **E**nergy) technology with mechanical vacuum massage of the skin.
The V-Touch system provides the treatments using the following specially-designed applicator:

The **ST** applicator, which was cleared for Viora's **Reaction** system under **K090221,** utilizes RF bipolar energy, through 2 electrodes. It is used for the treatment of relief of minor muscle aches and pain, relief of muscle spasm and temporary improvement of local blood circulation.

Intended Use Statement:

The Viora ***V-Touch*** is intended for dermatological procedures.

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

Predicate Devices:

Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Viora Reaction	**K090221**	July 1, 2009

Substantial Equivalence to Predicate Devices

The Viora ***V-Touch*** includes the ST applicator that is the same applicator that was cleared with the **Viora Reaction (K090221).**

Performance Standards:

V-Touch complies with

- ***IEC 60601-1*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- ***IEC 60601-1-2*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- ***IEC 60601-2-2*** - Medical Electrical Equipment-Part 2: Particular requirements for the safety of high frequency surgical equipment.

Performance Bench Tests and Conclusions

The ***V-Touch*** successfully passed validation and verification testing, including testing for RF power accuracy. Predicate comparison of the handpiece was unnecessary, since the predicate device uses the same handpiece. Bench testing demonstrated that the ***V-Touch*** is as safe and effective as the cleared predicate device.