

K090221

5-1



K090221

Page 1 of 3

510(k) Summary:

Reaction™ System

JUL - 1 2009

Company Name:
Viora Ltd.

Contact Person:
Omri Kessler
COO

Telephone: +972-3-5622248
Fax: +972-3-5622247
E-mail: omri@vioramed.com

Authorized US Agent:

Josef Luzon - CEO
Viora Inc.
30 Montgomery Street, Suite 660
Jersey City, NJ 07302

Telephone: (201) 332-4100
Fax: (201) 332-4200
E-mail: josef@vioramed.com

Date prepared: January 23, 2009

Trade Name:
Reaction™ System

Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Common/usual name: Massager, vacuum, light induced heating

Product Code: NUV, ISA

Regulation No.: 878.4810

Class: II

Panel identification: General and Plastic Surgery Panel.

**Predicate Device:**

VelaShape from Syneron Medical Ltd, Yokneam Elite, Israel, cleared under 510(k) # **K071872**;

VelaSmooth, Shaper from Syneron Medical Ltd, Yokneam Elite, Israel, cleared under 510(k) # **K050397**;

LPG Therapeutic Massager from LPG USA Inc, Fort Lauderdale, FL, USA, cleared under 510(k) # **K990445** and

Description of the device:

The Reaction™ system combines **CORE™** (Channeling Optimized RF Energy) technology with mechanical vacuum massage of the skin.

The Reaction™ treatment is indicated for the treatment of selected medical conditions such as relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite

The Reaction™ system provides the treatments using 3 specially-designed applicators that treat various areas of the body, including large and small areas.

The system includes five core modules: the **Console, the hand piece, and 3 treatment applicators: B-Contour, F-Contour and ST.**

The Reaction™ console houses the following components:

- Power supply
- Hand piece
- Vacuum pump
- RF Generator
- Main CPU
- Display unit

The hand piece allows the operator to adjust the treatment parameters of the RF power and intensity of mechanical vacuum massage.

The applicators incorporate operator panels and are used to adjust the treatment parameters of the RF power and mechanical vacuum manipulation.

**Indications for Use:**

The Reaction™ system is intended for the treatment of the following medical conditions, using the B-contour and F-contour applicators 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.

Using the ST applicator for delivering RF, the Reaction™ system is intended for the treatment of relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.

Substantial Equivalence:

The Reaction™ System using the B-contour and the F-contour applicators, has the same intended use and the same performance characteristics as the following predicate devices: **VelaShape** from Syneron Medical Ltd, Yokneam Elite, Israel, cleared under 510(k) # **K071872**; **VelaSmooth, Shaper** from Syneron Medical Ltd, Yokneam Elite, Israel, cleared under 510(k) # **K050397** and **LPG Therapeutic Massager** from LPG USA Inc, Fort Lauderdale, FL, USA, cleared under 510(k) # **K990445**.

When using the ST applicator, the Reaction™ System has the same intended use and the same performance characteristics as the RF application of **Cutera CMMCD** from Cutera Inc in Brisbane, CA, USA, cleared under 510(k) # **K080300** and the following predicate devices: **Intellect® SWD 100/ Senior Solutions** from Chattanooga Group in Hixson, TN, USA, cleared under 510(k) # **K083433** and **AutoTherm® 390, Model ME 390** from Mettler Electronics Corp in Anaheim, CA, USA, cleared under 510(k) # **K042554**.

The Reaction™ System is therefore substantially equivalent to those devices for each of the intended applications.

Conclusion -

The evaluation of the Reaction™ System does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.



JUL - 1 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Viora Ltd.
% Viora Inc.
Mr. Josef Luzon
Chief Executive Officer
30 Montgomery Street, Suite 660
Jersey City, New Jersey 07302

Re: K090221

Trade/Device Name: Reaction™ System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: NUV, ISA, ILY

Dated: June 18, 2009

Received: June 19, 2009

Dear Mr. Luzon:

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.

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

Page 2 - Mr. Josef Luzon

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/> 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K090221

Device Name: Reaction™ System

Indications for Use: The Reaction™ system is intended for the treatment of the following medical conditions, using the B-contour and F-contour applicators 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.

Using the ST applicator for delivering RF, the Reaction™ system is intended for the treatment of relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.

Prescription Use X OR
(Part 21 CFR 801 Subpart D)

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Quinn for me
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090221