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

August 1, 2016

Endymed Medical Ltd.
% Mr.Yoram Levy
QSite
31 Haavoda St.
Binyamina, Israel 30500
Israel

Re: K161199
Trade/Device Name: Endymed Contour Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: July 6, 2016
Received: July 12, 2016

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" (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,

Christopher J. Ronk -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)*
K161199

Device Name
EndyMed Contour Handpiece

Indications for Use *(Describe)*
The EndyMed Contour Handpiece is intended for the treatment of the following medical conditions; using the Contour applicator for delivery of non-thermal RF combined with massage:

- Relief of minor muscle aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- 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)

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)*

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

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K161199

510(K) SUMMARY

EndyMed Contour Handpiece

510(k) Number K161199

Applicant's Name: EndyMed Medical Ltd.
12 Leshem Street,
North Industrial Park,
Caesarea, 3088900 Israel
Tel: (972)4-630-9100
Fax: (972)4-630-9101

Contact Person: Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***EndyMed Contour Handpiece***

Preparation Date: April 14, 2016

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

Device Description:

EndyMed's ***EndyMed Contour Handpiece*** is a treatment handpiece to be attached to the FDA cleared EndyMed Imagine TC Skin Treatment System (Imagine K08346). The ***EndyMed Contour Handpiece*** combines suction module that creates vacuum energy and emits bipolar RF energy that flows between the electrodes to create thermal heating of the tissue.

The Vacuum is used for the massaging of deep tissues by creating mild to deep suction. The vacuum massage contributes to the sub-dermal and adipose tissues shrinkage and improves the contact surface between electrodes and tissue.

Intended Use Statement:

The ***EndyMed Contour Handpiece*** is intended for the treatment of the following medical conditions; using the Contour

applicator for delivery of non-thermal RF combined with massage:

- Relief of minor muscle aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510(k) No.	Date of Clearance
Venus Legacy CX	K143554	August 4, 2015
Viora V10 System	K150035	May 1, 2015

- **Venus Legacy CX (K143554)** – in respect to intended use and technological characteristics;
- **Viora V10 System (K150035) – in respect to intended use and technological characteristics;**

Reference Devices:

- **EndyMed Medical Ltd. Imagine (K083461)** - in respect to technological characteristics;

Performance Standards:

EndyMed Contour Handpiece complies with the following standards:

- IEC 60601-1:2005 / EN 60601-1:2006 Medical electrical equipment – part 1 General requirements for basic safety and essential performance, 3rd edition
- **IEC/EN 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 4th edition
- **IEC 60601-2-2:2009** 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

Summary of Technologies:

EndyMed Contour Handpiece implements RF energy and vacuum mechanical manipulation to achieve its intended use. The components of the EndyMed Pro, includes the console (with power supply, RF generator, suction module, CPU and display panel) and the applicators (with cable, connector to console, and vacuum pump).

Performance Data:

The safety and efficacy of the ***EndyMed Contour Handpiece*** were established by a series of performance tests. Lab performance tests, design validation and software verification and validation.
The ***EndyMed Contour Handpiece*** was validated for its power increase to 85W while maintaining a temperature between 40ºC and 45ºC and vacuum pressure of up to 500mBar.
Verification and testing have shown that the ***EndyMed Contour Handpiece*** device performs according to its specifications.

Summary of Clinical performance data:

The safety and efficacy of the ***EndyMed Contour Handpiece*** was evaluated by performance testing.

The ***EndyMed Contour Handpiece*** has the same intended use, clinical indication and technology and no clinical studies were necessary to show substantial equivalency with its predicate devices.

Substantial Equivalence:

EndyMed Contour Handpiece device has the same intended use, clinical indication and basic technology as its predicate devices.
The envelope of power, frequency and vacuum parameters of the submitted ***EndyMed Contour Handpiece*** is covered by the envelopes of its predicate devices.
The ***EndyMed Contour Handpiece***, the Venus Legacy CX device and the K150035 Viora V10 System are based on the same core technology of RF heating and vacuum massaging for the same indications for use. The design and components in the subject device including the console and the applicators are the same. The minor technological differences do not alter device core technology or performance. The performance of the ***EndyMed Contour Handpiece*** is substantially equivalent to that of the Venus Legacy CX device and the K150035 Viora V10 System, as demonstrated in testing.
Any minor differences in the human interface and accessories design do not raise any new types of safety and effectiveness issues, as verified by performance testing. Therefore the ***EndyMed Contour Handpiece*** is substantially equivalent to its predicate devices.

Conclusions:

The ***EndyMed Contour Handpiece*** is based on the same intended use and indications for use, technological characteristics, and principles of operation. As a result the ***EndyMed Contour Handpiece*** device is substantially equivalent to the Venus Legacy CX and the K150035 Viora V10 System predicate devices