



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

December 18, 2015

EndyMed Medical Ltd.  
c/o Mr. Yoram Levy, Qsite  
31 Haavoda St.,  
Binyamina, ISRAEL 30500

Re: DEN150005  
Newa™  
Evaluation of Automatic Class III Designation – *De Novo* Request  
Regulation Number: 21 CFR 878.4420  
Regulation Name: Electrosurgical device for over-the-counter (OTC) aesthetic use  
Regulatory Classification: Class II  
Product Code: PAY  
Dated: January 13, 2015  
Received: January 16, 2015

Dear Mr. Levy:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Newa™, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indication:

*The EndyMed Newa™ is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult women with Fitzpatrick Skin Types I-IV.*

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Newa™, and substantially equivalent devices of this generic type, into class II under the generic name, Electrosurgical device for over-the-counter aesthetic use.

FDA identifies this generic type of device as:

**Electrosurgical device for over-the-counter aesthetic use.** An electrosurgical device for over-the-counter aesthetic use is a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon

which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On January 16, 2015, FDA received your *de novo* requesting classification of the Newa™ into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Newa™ into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Newa™ with the following indication:

*The EndyMed Newa™ is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult women with Fitzpatrick Skin Types I-IV.*

can be classified in class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

| <b>Identified Risk</b>                               | <b>Mitigation Measure</b>   |
|--|---|
| Infection  | Cleaning Validation<br>Labeling   |
| Adverse Tissue Reaction                              | Biocompatibility  |
| Skin Overheating / Burn                              | Clinical Performance Testing<br>Non-clinical Performance Testing<br>Software Verification, Validation<br>& Hazards Analysis<br>Labeling |
| Electromagnetic Interference / Electrical Shock      | Electromagnetic Compatibility Testing<br>Electrical Safety Testing<br>Labeling  |
| Worsening Aesthetic Outcomes                         | Clinical Performance Testing  |
| Use Error  | Usability Study<br>Labeling   |
| Failure to Identify Correct Population and Condition | Label Comprehension & Self-Selection Study<br>Labeling  |

In combination with the general controls of the FD&C Act, the Electrosurgical device for over-the-counter aesthetic use is subject to the following special controls:

1. Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics

must be tested: over-heating, power accuracy radiofrequency, pulse cycle, waveform, pulse duration, and device characterization parameters.

2. Label comprehension and self-selection performance evaluation must demonstrate that the intended over-the-counter users can understand the package labeling and correctly choose the device for the indicated aesthetic use.
3. Usability performance evaluation must demonstrate that the over-the-counter user can correctly use the device, based solely on reading the directions for use, to treat the indicated aesthetic use.
4. Clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use to achieve the intended aesthetic results.
5. The patient-contacting components of the device must be demonstrated to be biocompatible.
6. Instructions for cleaning the device must be validated.
7. Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety, including the mechanical integrity, of the device.
8. Software verification, validation and hazard analysis must be performed.
9. Labeling must include:
  - a. Warnings, precautions, and contraindications to ensure the safe use of the device for the over-the-counter users.
  - b. A statement that the safety and effectiveness of the device's use for uses other than the indicated aesthetic use are not known.
  - c. A summary of the clinical information used to establish effectiveness for each indicated aesthetic usage and observed adverse events.

In addition, this is an over-the-counter device and must comply with 21 CFR Part 801 Subpart C. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Electrosurgical device for over-the-counter (OTC) aesthetic use they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Long Chen, PhD at (301)796-6389.

Sincerely,

**Jonette R. Foy -S**

Jonette Foy, Ph.D.  
Deputy Director  
for Engineering and Science Review  
Office of Device Evaluation  
Center for Devices and  
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