

**DE NOVO CLASSIFICATION REQUEST FOR  
NEWA™**

**REGULATORY INFORMATION**

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 over-the-counter non-invasive aesthetic use.

**NEW REGULATION NUMBER:** 21 CFR §878.4420

**CLASSIFICATION:** II

**PRODUCT CODE:** PAY

**BACKGROUND**

**DEVICE NAME:** NEWA™

**SUBMISSION NUMBER:** DEN150005

**DATE OF DE NOVO:** JANUARY 16, 2015

**CONTACT:** ENDYMED MEDICAL LTD, CAESAREA, ISRAEL  
% YORAM LEVY, QSITE  
HAAVODA 31, BINYAMINA 30500, ISRAEL

**REQUESTER'S RECOMMENDED CLASSIFICATION:** II

**INDICATIONS FOR USE**

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 who have Fitzpatrick Skin Types I-IV.

**LIMITATIONS**

The sale, distribution, and use of Newa™ are for over-the-counter (OTC) use in accordance with 21 CFR 801 subpart C.

Limitations on device use are also achieved through the following statements included in the User Manual:

“The Newa OTC home use device is intended for women who have mild to moderate facial wrinkles and want to reduce them using a home device. The device is intended for

adult women who have Fitzpatrick Skin Types I-IV” (see Figure 1 for Fitzpatrick Skin Type scale).

Contraindications:

“DO NOT USE THE NEWA™ IF YOU HAVE ANY OF THE FOLLOWING: Have an implanted pacemaker, arrhythmias or any other severe known heart disorder. (Flow of electrical energy through the body may damage the pacemaker and cause dangerous heart arrhythmias).

Warnings:

“Since Safety and effectiveness of the device was not tested in individuals with the following conditions it is NOT advised that you use the device if you”:

- Are pregnant or breastfeeding. (Safety and effectiveness of the device was not tested )
- Have Fitzpatrick skin type V or VI (dark skin). (Safety and effectiveness of the device when used in individuals with darker skin or who may be prone to skin discoloration and hypertrophic scars (also known as keloids) has not been established.)
- Suffer from autoimmune disorders or diabetes. (Skin healing in these cases may be impaired)
- Have any lesions on the treatment area
- Have blood clotting disorders
- Use blood thinning medications. . (The mechanical massage by the device may induces skin hematomas)
- Are using or have used Isotretinoin (Accutane) within the past 6 months. (When using Isotretinoine the skin is more fragile than usual and maybe easily injured by any mechanical massage)

“Since Safety and effectiveness of the device was not tested in individuals with the following conditions it is NOT advised that you use the device if you:

- Are male.
- Have severe, deep wrinkles.
- Use in subjects without total removal of facial hair may result in follicular burn in these areas.

“Since effectiveness of the device was not tested in individuals with the following conditions the effectiveness of the device is unknown if you:

- Have moderate wrinkles under the chin  
Are younger than 37 years old.

“Do not use the Newa™ over the eyebrows, eyelids, lips, ears, breasts or genital area. Eye damage, damage to glands, sensitive and delicate skin, and other tissue may occur. Follow instruction for use exactly as directed for your safety”

“Patients with visual difficulties should not use the device.”

“Have any implantable metal device or body piercing in the treatment area. (Flow of electrical energy through the implanted metal may heat the object and cause burns).”

For a complete list of warnings, precautions and contraindications, please refer to the device labeling.



Figure 1: Fitzpatrick skin type scale

### **DEVICE DESCRIPTION**

The Newa™ is an OTC, home use hand held device generating pulses of radiofrequency (RF) energy that are emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive, non-ablative device consisting of:

- User interface
- Programmable logic controller (PLC)
- RF power module
- Power supply
- RF electrodes

The user interface allows the selection of heating level: high, low or off. The PLC is a specially configured computer that provides the operational and safety function of the system. The RF power module provides RF energy to the active tip electrodes, producing a sinusoidal signal at a 1MHz frequency. This device is supplied non-sterile. Figure 2 shows the external views of the Newa™ from different directions.



Figure 2: The external views of the Newa™ (Top left: upper view - power button; Top right: bottom view – electrodes; Bottom: side view – power level switch)

As shown in Figure 3, the active tip of the Newa™ device is composed of 3 pairs of bipolar electrodes arranged to deliver RF energy. It allows delivery of the required power to the tissue, up to 10W ( $\pm 20\%$ ) but with diminished flow of energy on the surface of the skin.

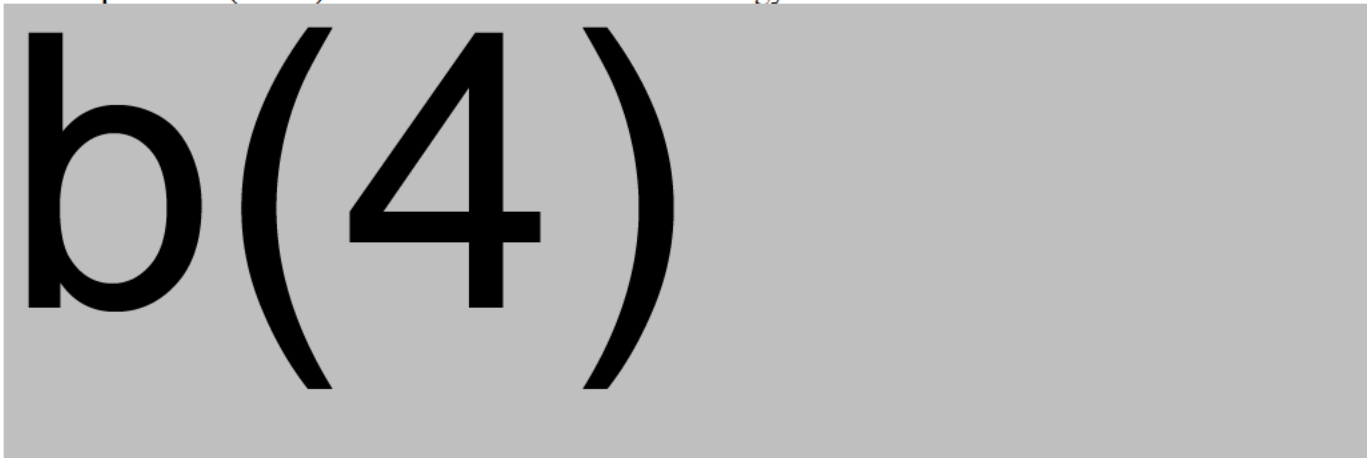


Figure 3: Bipolar RF electrodes pairs

#### Additional Components

The Newa™ is supplied with the following additional components:

- Treatment gel (ECO-MED PHARMACEUTICALS ECOGEL 200 Ultrasound gel, K955246). The treatment gel is intended to improve electrical contact with the skin (lower the impedance) and act as a lubricant to aid in the movement of the device.
- User manual
- Quick reference guide
- Power supply
- Storage bag
- Instructional DVD

The user is instructed to apply the treatment gel to the electrodes, push the power button and treat the skin in a circulatory movement for 4 minutes per treatment area (10cm x 5cm). At the end of

4 minutes, the user feels a mild vibration and RF emission stops. The same procedure is used to treat all remaining facial treatment areas (see Figure 4).

Device Characteristics

Intended Use	Treatment of Mild to Moderate Facial Wrinkles and Rhytides
Use Environment	Over-the-Counter
Energy Source	RF Bipolar Energy
Treatment Area	Facial (6 areas, as described in Figure 4)
Treatment Regimen	4 minutes each area, 5x/week for 4 weeks
Treatment Method	Circular Motion
Electrode Dimensions, Width/Length	b(4)
Surface Between Bipolar Pair	b(4)
Pulse	240 seconds
Area Covered/Pulse	b(4)
Maximum Energy Density	b(4)
Input Power	100-240V, 50-60Hz
Power Consumption	10 W
Dimensions	73 mm, 37 mm, 120 mm
Weight	70 g



Figure 4: Six “treatment areas”- two on each cheek and two under the chin.

Safety Features

The Newa™ is designed with the following safety features:

- A built-in thermal sensor to monitor the skin temperature that will stop RF energy delivery when the surface temperature exceeds 42°C.
- A built-in movement sensor that will stop energy delivery when the device is stationary.
- A visual user interface with a steady LED that indicates the device is ready for use and a blinking LED that indicates active RF delivery.
- A built-in timer that will stop RF energy delivery after 4 minutes of use.
- Vibratory signal that alerts the user when the treatment per area is complete (4 minutes).

## **SUMMARY OF NONCLINICAL/BENCH STUDIES**

Non-clinical performance testing was conducted to demonstrate the Newa™ would perform as anticipated for its intended population.

### **BIOCOMPATIBILITY/MATERIALS**

The parts that come into contact with the treated tissue include the electrodes (b(4) (b(4) ) and the shell (b(4) ). They are the same as that of the Newa prescription home use device (K130793), which were tested according to ISO 10993-1 and USP Class VI tests, and met the requirements specified for up to 30 days contact with human tissue.

### **STABILITY/STERILITY**

The Newa™ is supplied non-sterile and is reusable. Cleaning instructions for the device are included in the User Manual. The user is recommended to moisten a soft cloth with water and mild soap, and wipe the outside of the device, including the active tip area. A cleaning validation protocol and report were provided in the submission, which demonstrate that the cleaning instructions are adequate. Additionally, the device is intended and labeled only for a single user to prevent contamination between users.

Based on the bench testing data, a functional life of 5 years was proposed for the Newa™, when used according to the instructions of use. This proposed functional life is based on functional testing of the device and the expected usage of the device per the instructions for use. This proposed functional life, which is calculated based on the expected usage of the device, is reasonable and acceptable.

### **ELECTROMAGNETIC COMPATIBILITY (EMC) AND ELECTRICAL SAFETY**

The following electrical safety and EMC testing was performed:

- IEC 60601-1:2005/EN 60601-1:2006, General safety standard: safety requirements for medical electrical systems;
- IEC 60601-1-2:2007, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Electromagnetic compatibility.
- IEC 60601-1-11:2010, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.

The Newa™ passed all relevant portions of the testing and demonstrated the electrical safety for the Newa™ to be used in a home environment.

### **SOFTWARE**

The Newa™ software is implemented as firmware running on a micro-controller embedded into the device motherboard. The software and micro-controller is the same as that previously cleared for the Newa™ prescription home use device (K130793). The Agency considers the Newa™ software to be a moderate level of concern (LOC) because inadvertent software errors could result in skin burns to the patient.

All of the elements of software information corresponding to moderate LOC devices as outlined in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005) have been provided. Adequate documentation describing the software development program was provided. The following verification and validation (V&V) testing was conducted to address the potential hazards with satisfactory results: system initialization, power button functionality, power down system, LEDs indications, vibration indication, and temperature detection. In addition, the software development procedures provide the foundation that the software will operate in a manner as described in the specifications. Overall, the software documentation included in the *de novo* request is in sufficient detail to provide reasonable assurance that the software performs as intended and all software-related risks have been adequately mitigated.

#### **PERFORMANCE TESTING – BENCH**

Bench testing was conducted per IEC standard 60601-1 to demonstrate that the Newa™ device performs as expected under anticipated conditions of use. This testing included verification of the mechanical integrity of the device according to the relevant sections of the IEC 60601-1 standard. The following bench testing was conducted to demonstrate the device performance characteristics:

- **Over-heating safety**  
The device was tested to ensure that it does not overheat the skin. A thermistor is embedded in the device, which constantly measures the skin temperature and ceases the operation of the RF when the temperature rises above 42 °C. This temperature was determined to be acceptable based on published information from the National Institute for Standard and Technology ([http://www.nist.gov/fire/fire\\_behavior.cfm](http://www.nist.gov/fire/fire_behavior.cfm)) which state that human skin begins to feel pain at 44°C and may start to develop skin burns at 48°C. The purpose of this performance test was to validate the temperature measuring and RF control functions. The required acceptance criterion was that the temperature measured on the surface of the gel and electrodes should not rise above 42±0.5 °C during the testing. As the test began, the temperature of the subject was measured at 37.1°C. Temperatures rose up to 42.1°C ,at which point the RF energy delivery stopped (LED blinking in green instead of blue) and the temperature started to decline.
- **Power accuracy**  
The device was validated for power accuracy at 10 Watts on a 360Ω load, which is appropriate as the reference of the average load of a user. The listed specification for power accuracy was 10 Watt ±20% = 8-12 Watt. The measured total power was 10W, indicating that the device met the acceptance criterion.
- **Newa™ parameter validation**  
The device was tested for its radio frequency, pulse cycle, wave form and pulse duration. The accepted values were: 1 MHz radio frequency, 750ms pulse cycle, modified sine wave (square wave) wave form, 300ms pulse duration for “1”

mode, and 450ms pulse duration for “2” mode. The test results were at the declared values.

Bench testing demonstrated that the device performs as expected under anticipated conditions of use.

#### **PERFORMANCE TESTING – ANIMAL**

No animal testing was performed with the subject device.

### **SUMMARY OF CLINICAL INFORMATION**

#### **Clinical Study**

A clinical study was conducted with a primary goal of validating safety of independent treatment with the Newa™ for facial wrinkle reduction by intended users. The secondary goal of this clinical study was to evaluate the effectiveness of wrinkle reduction by the Newa™ and to measure user satisfaction.

A total of 69 participants (average age  $54.4 \pm 8.1$  years; age range 37-72) were enrolled in the prospective, single center study after meeting the selection criteria and signing an informed consent form.

The independent home treatment consisted of performing at least 5 wrinkle reduction treatments in a week at home for four weeks. Patients were provided with a diary and were instructed to document any side effects related to the treatments. Patients were instructed to treat the designated 6 areas of the face 4 minutes each. During the 4 minutes, the area of skin is heated. Patients had the option to choose two treatment levels: High and Low. They were instructed to start out with the High setting and change to the Low setting if warmth was uncomfortable. Patients were instructed to treat any of the six areas according to their needs and comfort.

#### **Primary Endpoint (Safety)**

Patients were scheduled for 3 categories of task performances and independent treatment visits under investigator’s observation. There were a total of 14 tasks, which include the following: preparing the user for treatment (3 tasks), preparing the device for treatment (3 tasks) and treatment performance (8 tasks).

Each patient had 9 study visits. In the first and two subsequent visits, the independent treatment for wrinkle reduction was performed under investigator’s observation. Patients were asked to rate pain level, and note any problem/difficulties during the treatments.

Following task performance, patients were provided with the Newa™ and were instructed to perform treatments independently at home, 5 times a week, for 4 weeks.

Patients were scheduled for follow-up visits during and at the end of the 4-week independent home treatment, and 1 and 3 months following treatment completion. Patients were asked to detail any side effects or questions or difficulties of the treatments or devices. At the 1 month and 3 months follow-up, photographs of the patients were also taken.



Patients were given a patient satisfaction questionnaire of 5 questions at the end of the 4-week independent home treatment, and at 1 and 3 months follow up visits to address usability concerns and level of satisfaction.

To evaluate Secondary Endpoint Effectiveness:

Three independent board-certified dermatologists compared the photographs of patients taken at baseline (prior to treatment initiation) to those taken right after treatment completion, and 1 and 3 months after the completion of the independent home treatment. The Fitzpatrick Wrinkle Severity Scale is a clinically validated assessment tool used to assess skin wrinkle severity and elastosis by evaluating photographs of the whole face (Table 1).

<b>Table 1 - Fitzpatrick Wrinkle Severity Scale</b>			
<b>Class</b>	<b>Wrinkling</b>	<b>Score</b>	<b>Degree of Elastosis</b>
<b>I</b>	Fine wrinkles	1-3	Mild (fine textural changes with subtly accentuated skin lines)
<b>II</b>	Fine to moderate-depth wrinkles, moderate number of lines	4-6	Moderate (distinct papular elastosis [individual papules with yellow translucency under direct lighting] and dyschromia)
<b>III</b>	Fine to deep wrinkles, numerous lines, with or without redundant skin folds	7-9	Severe (multipapular and confluent elastosis [thickened yellow and pallid] approaching or consistent with cutis rhomboidalis)

Results:

Sixty-two patients out of sixty-nine patients (average age  $54.4 \pm 8.10$ ) completed the study and follow up visits. All patients were female with an age range of 37 to 72. Seven patients did not complete all the follow up visits as a result of lack of time.

Safety:

Adverse effects or side effects were documented on the 4 follow-up visits, which took place once a week during the 4-week independent home treatments. None of the following specific adverse events were reported: burns, skin breakdown or scarring. Two users reported moderate redness that subsided spontaneously in less than 30 minutes. Fifty-nine users reported the post treatment redness was minimal and subsided in less than 15 minutes after treatment. There was one report of a 1-2 cm erythema that was resolved with application of a non-medical moisturizer after 24 hours. There were no significant adverse events related to the use of the device on the face or submandibular area.

Effectiveness:

This study employed an effectiveness evaluation tool that was validated for facial wrinkles but not submandibular wrinkles. Full face photographs were used to assess effectiveness; therefore, no conclusions can be made for individual treatment areas (e.g., cheeks or submandibular region). According to the study, downgrade of at least 1 score on the Fitzpatrick Wrinkle Severity Scale score was seen in 91.93%, 96.77%, and 98.39% of the patients, as reported by the

first, second and third reviewers, respectively (results are summarized in Table 2 below). A one-point improvement is generally accepted by patients as a meaningful improvement when using low-risk devices. Score differences were found to be statistically significant for both the comparison of the baseline score to the score reported 4 weeks post-treatment, and to that reported 3 months following completion of the treatment. In comparing the Fitzpatrick Wrinkle Severity Scale scores of 4 weeks post-treatment to the 3 months follow up, the score improvement was not statistically significant, which suggests that the improvements from baseline are durable up to 3 months, but that additional improvement from the end of treatment are unlikely once treatment is discontinued. The Newa™ has not been evaluated for treatment of wrinkles under the chin.

A patient was considered a success if at least 2 out of the 3 independent dermatologists agreed that the patient has reached at least one degree of wrinkle score reduction (per the Fitzpatrick Wrinkle Severity Scale) when comparing the score obtained at the 4-week follow up to the baseline wrinkle score. Fifty-nine patients (95%) in the study met this predefined criterion.

<b>Table 2 – Effectiveness Results Calculated Based on Completer Case (N=62)</b>		
<b>Success rate at the end of the 4-week treatment:</b>		
<b>Reviewer #1</b>	91.93% (57/62)	[82.17%, 97.33%]
<b>Reviewer #2</b>	91.93% (57/62)	[82.17%, 97.33%]
<b>Reviewer #3</b>	90.32% (56/62)	[91.34%, 99.96%]
<b>≥ 2 agree</b>	95.16% (59/62)	[86.50%, 98.99%]
<b>Success rate at 3 months follow-up after the last treatment:</b>		
<b>Reviewer #1</b>	91.93% (57/62)	[82.17%, 97.33%]
<b>Reviewer #2</b>	96.77% (60/62)	[88.83%, 99.61%]
<b>Reviewer #3</b>	98.39% (61/62)	[91.34%, 99.96%]
<b>≥ 2 agree</b>	100% (62/62)	[94.22%, 100%]

The study success criterion for treatment effectiveness of home use Newa™ was defined as “at least 75% of patients being a success”. Based on the data reported in Table 2, the study success criterion for treatment effectiveness using the Newa™ for independent wrinkle reduction treatment was met.

Patients were also asked to rate their satisfaction with the device using the five questions below. A score of 5 was defined as “Very Satisfied” while a score of 1 was “Very dissatisfied.”

1. Over all, how satisfied are you with the Newa™ device?
2. How satisfied are you with the safety of performing wrinkle reduction treatment with Newa™ device?
3. How satisfied are you with the ease of treatment with Newa™ device

4. How satisfied are you with the ease of learning to use the Newa™ device
5. How satisfied are you with the wrinkle reduction obtained by the Newa™ device? For this question, the following scoring methodology was used:
  - 5 – >80%
  - 4 – ≤ 80%
  - 3 – < 50%
  - 2 – < 20%
  - 1 – No improvement

The data from this questionnaire show that subjects were generally satisfied with the Newa™, and rated both the safety and the ease of learning well. For effectiveness, 54 out of the 62 subjects (93.5%) noted at least a 20% reduction in their wrinkles (as defined by a score of 3 or higher), and 32 out of 62 subjects noted a reduction of 50% or more (as defined by a score of 4 or higher).

### **Usability Study**

A usability study was conducted as part of the clinical study. The study was divided into several steps. There were 3 tasks the user needed to complete in preparation of using the device and these were completed by 100% of the subjects. These steps included removal of jewelry from the treatment areas, thoroughly cleaning and drying of the face, and dividing the face into 6 treatment areas according to Figure 4.

The next 3 tasks were associated with preparing the device for use, and again 100% of subjects completed these correctly. These steps included plugging the device into the electrical outlet and paying attention to the light signal, checking the expiration date of the gel, and applying the treatment gel on the treatment tip of the device.

Finally, there were 8 tasks associated with using the device correctly, and again 100% of subjects completed these correctly. These tasks included: spreading the gel that was applied on the tip of the device with a circular motion to the borders of the treatment area; clicking the trigger button to start RF emission and treating the entire treatment area in a constant circular motion and verifying that the motion is constant; checking whether the skin is comfortably heated and continuing the circular motion on the treated area for 4 minutes; checking whether the skin temperature is too low and, if so, decreasing the radius of the circles and/or decreasing the speed of the circular motion, checking whether the subject manages to increase heat level; checking whether the skin temperature is too high and, if so, increasing the radius of the circles and/or speeding up the circular motion, checking whether the subject manages to decrease the heat level; continuing the circular motion on the tested area for 4 minutes until the RF emission stopped; and re-applying the gel to the tip of the device and repeating the treatment procedure on the next skin area.

The use scenario performance results of the first independent treatment are summarized in Table 3. All of the above tasks were performed by the subjects who were observed through a one-way mirror to insure correct procedures by the user.

<b>No</b>	<b>Use scenarios</b>	<b>Pass</b>	<b>Pass (%)</b>
1	Preparing yourself for treatment (3 tasks)	62	100 %
2	Preparing device for treatment (3 tasks)	62	100 %
3	Treatment performance (8 tasks)	62	100 %

**Labeling Comprehension/Self-Selection Study**

A labeling comprehension and self-selection study was conducted. The primary goal was to demonstrate that the intended OTC users can understand the package labeling and correctly choose this device for themselves to treat facial wrinkles and rhytides.

The primary endpoint was the proportion of study participants who make a correct self-selection decision. 85% was the target for a self-selection success rate. The secondary endpoint was the validation of the responses to a self-selection questionnaire by level of agreement between subject’s results and medical expert results.

There was an initial screen step to insure that the subjects could speak, read and understand English. In addition, subjects who worked in the healthcare field, who worked in the field of Contract Research, and individuals who had participated in a recent clinical study were excluded from the study. Following the initial screening, all subjects were given the Rapid Estimate of Adult Literacy in Medicine (REALM) test to determine their literacy level in order to insure that at least 20% of the subjects had below a 9th grade reading level.

The actual test consisted of giving the subject the sleeve that would be used as the box labeling for the device and allow them sufficient time to read the sleeve. Once they had read the sleeve, the subjects were asked to decide if purchase of the device was correct for them. Correct answers could be “yes” or “no” and each subject was then asked to state why the purchase or no purchase decision was made.

Once the subject completed the testing and left, the interviewer who was trained in assessing wrinkle severity made a separate assessment of the subject’s wrinkles severity level. The medical history of the subject, the subject’s decision and reasons for the decision, and the interviewer’s assessment were then provided to a blinded outside expert for a determination whether or not the subject had correctly self-selected.

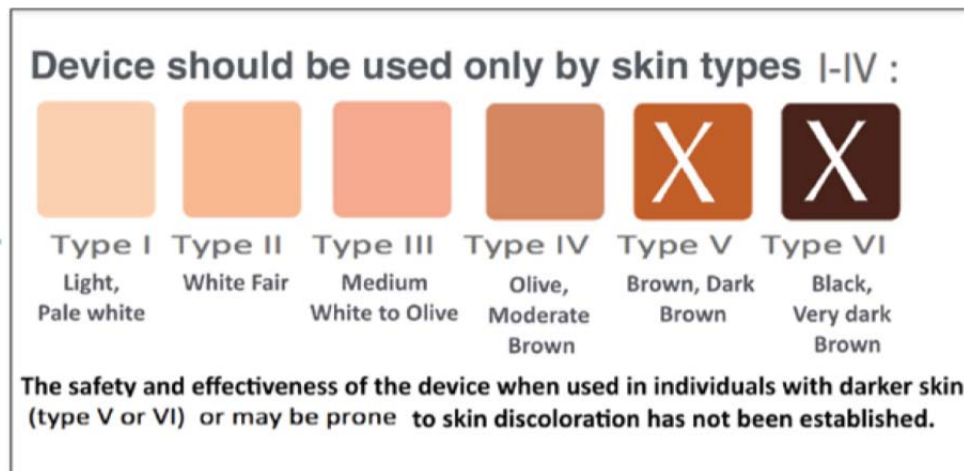
Of the 247 subjects enrolled into the study, 195 (78.9%) stated they could use the device and 52 (21.1%) stated they could not use the device. All 52 who stated they could not use the device made the correct self-selection decision. Of the 195 who said they could use the device, 180 subjects (92.3%) made a correct self-selection decision, which is an acceptable success level ( $\geq 85\%$ ). Validation test (the Inter Rater Agreement test - Kappa test) indicated a strong agreement ( $k=0.81$ ) between the subjects’ self-selection decision and expert opinion whether it would be correct for these subjects to use the Newa™ at home.

**LABELING**

Labeling has been included which consists of a User Manual, a Quick Reference Guide, and Box Labeling. The User Manual and Quick Reference Guide summarize the main steps for the independent home use treatment.

The outer package labeling includes the following:

- When to use? (Indication)
- What is the Newa™? Why you use the device?
- Who can benefit from the Newa™ treatments?
- Using the Newa™  
It is suggested to use the Newa™ up to 5 times a week, up to 6 treatment areas per session, 4 minutes per area, not more than one treatment a day, for 4 consecutive weeks.
- Using cannot use it? (Contraindications)



- What you must do to avoid serious harm? (Warnings)
- What you must do to avoid other harm? (Precautions)
- Manufacturer's name and address, model name, serial number and date of manufacture and other information presented as symbols.

**RISKS TO HEALTH**

Table 4 below identifies the risks to health that may be associated with use of Newa™ and the measures necessary to mitigate these risks.

<b>Table 4 – Identified Risks to Health and Mitigation Measures</b>	
<b>Identified Risk</b>	<b>Mitigation Measure</b>
Infection	Cleaning Validation Labeling
Adverse Tissue Reaction	Biocompatibility
Skin Overheating / Burn	Clinical Performance Testing

	Non-clinical Performance Testing Software Verification, Validation & Hazards Analysis Labeling
Electromagnetic Interference / Electrical Shock	Electromagnetic Compatibility Testing Electrical Safety Testing Labeling
Worsening Aesthetic Outcomes	Clinical Performance Testing
Use Error	Usability Study Labeling
Failure to Identify Correct Population and Condition	Label Comprehension & Self-Selection Study Labeling

**SPECIAL CONTROLS**

In combination with the general controls of the Food, Drug & Cosmetic Act, the **Electrosurgical device for over-the-counter (OTC) 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 OTC users can understand the package labeling and correctly choose the device for the indicated aesthetic use.
3. Usability performance evaluation must demonstrate that the layman 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 (EMC) 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 OTC 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.

#### **BENEFIT/RISK DETERMINATION**

The risks of the Newa™ device are based on the nonclinical data as well as data collected in clinical studies described above. The likelihood for each of the listed risks has not been quantified but is expected to be extremely low, given the steps taken through the bench testing, labeling, usability study, label comprehension and self-select study, and clinical performance testing that has been performed to mitigate each of the listed Newa™ device risks. The risks associated with use of the device include the following: infection, adverse tissue reactions, skin overheating/burn, electromagnetic interference, worsening aesthetic outcomes, user error, and failure to identify correct population and condition.

All of the above listed risks may also result in non-serious adverse events depending on the extent of adverse event effect. Based on the clinical performance testing provided, the expected adverse events include skin redness and minor swelling in the treatment area, pain, damage to natural skin texture (crusting, blister, burn), or fragile skin. Based on the clinical performance testing provided, the probability of each of these potential adverse events is low.

The probable benefits of the Newa™ device are based on the clinical performance testing provided, and the improvements seen on the patient wrinkles severity reduction scores is substantial. Additionally, the majority of the patients reported to be satisfied with the level of improvement.

The Newa™ device seems to be of relative low risk due to automatic shut off and relatively low temperature. Patients reported acceptable rates of satisfaction and the adverse event profile shows few moderate events.

Additional factors to be considered in determining probable risks and benefits for the Newa™ device include: the limitations of the use of the device per the instructions in the labeling. One such limitation is that the device should not to be used for retreatment. Because the device has not been tested for repeat treatments, labeling advises against this approach. Another limitation

of the device is that it only recommended for subjects with Fitzpatrick skin color types I-IV. The safety and effectiveness of the Newa™ device has not been established for subjects with Fitzpatrick skin color types V and VI. The device has not been tested in individuals with darker skin or who may be prone to skin discoloration and hypertrophic scars (also known as keloids). Both limitations are described in the package labeling.

Only women aged 37 – 72 years of age with Fitzpatrick skin types I through IV were enrolled in the study. Given the potential differences in skin thickness between men and women, the indications for use for this device was limited to adult women only. Furthermore, no data was provided to establish the effect the device may have on facial hair. Based on this concern, the statement “Use in subjects without total removal of facial hair may result in follicular burn in these areas” was added to the proposed labeling. Labeling has been included to clearly identify the patient population that was studied, and inform patients that the safety and effectiveness of the device was not tested for the other populations (e.g., men, age <37).

The label comprehension and self-selection study was conducted to assess the effectiveness of the package labeling for the intended OTC users to understand and correctly choose this device for themselves to treat facial wrinkles and rhytides. The Newa™ device labeling appears to mitigate potential user error associated with device use and to allow the user to identify the correct population and condition for the device. The label comprehension and self-selection study demonstrated that the intended OTC users can understand the package labeling, and correctly choose this device for themselves to treat facial wrinkles. These risk mitigations have been carefully reviewed and appear to be acceptable.

In conclusion, given the available information summarized above, the data support that for subjects with Fitzpatrick skin color types I-IV, the probable benefits outweigh the probable risks for the Newa™ device to treat facial wrinkles. Sufficient evidence has been provided to establish special controls that can adequately mitigate the risks to health for the use of Newa™ for its intended patient population. The device provides substantial benefits and the risks can be mitigated by the use of general and identified special controls.

#### **CONCLUSION**

The *de novo* for the Newa™ is granted and the device is classified under the following:

Product Code: PAY

Device Type: Electrosurgical device for over-the-counter (OTC) aesthetic use

Class: II

Regulation: 21 CFR 878.4420