September 21, 2018

Ward Photonics LLC
% Jeff Brown
Senior Consultant
Jeff Brown Lifescience
1260 Bell View Circle
Sandy, Utah 84094

Re: K180338
Trade/Device Name: Cellulize
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: February 7, 2018
Received: February 7, 2018

Dear Jeff Brown:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K180338

Device Name
Cellulize

Indications for Use *(Describe)*

Cellulize® is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

The Massager component is indicated for the 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# Section 6 - 510(k) Summary For

# Cellulize

**1. Submission Sponsor**

Ward Photonics LLC
1980 N. Atlantic Avenue, Ste. 1030
Cocoa Beach, FL 32931 USA
Phone: 1-800-392-5950
Fax: 1-800-392-5950
Contact: Terry Ward, Managing Director

**2. Submission Correspondent**

Jeff Brown Lifescience
1260 Bell View Circle
Sandy, UT 84094
Telephone: (801) 633-9660
Contact: Jeff Brown, Managing Partner
Email: jeffbrown144@gmail.com

**3. Date Prepared**

September 20, 2018 (revised submission 180920-3)

**4. Device Identification**

| | | |
|---|---|---|
| Trade/Proprietary Name: | CELLULIZE | Pure Wave Massager |
| Common/Usual Name: | Fat Reducing Low Level Laser | Massager, Therapeutic, Manual |
| Classification Name: | Low level laser system for aesthetic use | Therapeutic massager |
| Classification Regulation: | 878.5400 | 890.5660 |
| Product Code: | OLI | LYG |
| Device Class: | Class II | Class I |
| Classification Panel: | General & Plastic Surgery | Physical Medicine |

5. **Class II Special Controls for Low Level Laser System for Aesthetic Use**
The guidance document, "Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use," outlines the special controls, along with general controls, that are sufficient to provide reasonable assurance of the safety and effectiveness of the low level laser system for aesthetic use. Therefore, this submission and supporting exhibits will show that (1) Ward Photonics, and Cellulize, conform to the general controls of the Federal Food, Drug & Cosmetic Act (the FD&C Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) the specific risks to health associated with the low level laser system for aesthetic use identified in the guidance are addressed, and (3) Cellulize is substantially equivalent to the predicate device.

6. **Photographs and Drawings of the Device**
Cellulize is generally described as a pole-mounted free-standing device as shown in the photo to the right. The device is described in greater detail using a series of schematic drawings attached as Exhibits 13B (1-7).


**Cellulize pole mounted free-standing device.**

7. **Legally Marketed Predicate Device(s)**
The Cellulize is substantially equivalent to the following predicate devices:
   - Verju Laser, (K130922) by Erchonia Corporation.
   - Photonica Professional, (K160880) by Ward Photonics.

8. **Device Description**
The Cellulize is a non-invasive green light system with a power output of 105mW/cm2, consisting of 150 light emitting diodes (LEDs) that emit visible light at nominal wavelength of 532nm ± 3nm (visible green light spectrum) and a spectral bandwidth of 10nm. Cellulize® is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The Massager component is indicated for the temporary reduction in the appearance of cellulite.

The components of the device include a mobile pole cart, controller console which plugs into a hospital-grade isolation transformer (attached with a bracket clamp to the pole cart), LED array mounted on an articulated arm (attached with a bracket clamp to the mobile pole cart), digital timer pre-selected for 8-minutes or 20-minutes, on/off switch, and a hospital-grade power cable. The articulated arm allows the light fixture to be positioned in a wide variety of functional positions. The knuckles and joints on the arm allow the light fixture to be rotated, tilted, and raised/lowered independently. The timer is set to a preset value of 8 minutes for circumference reduction treatment via a validated internal timer delay relay. The light fixture is positioned 17cm (6.8") from the patient's skin to deliver the standard dose output intensity of 105mW/cm$^2$ and standard energy dose of 50 J/cm$^2$ with 8 minutes. Cellulize does not use any software.

**9. Indication for Use Statement**

Cellulize® is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
The Massager component is indicated for the temporary reduction in the appearance of cellulite.

**10. Risk of Ocular Injury**

Cellulize was subjected to bench testing in order to demonstrate that the system meets all design specification and performance requirements.

- IEC 60601-1-2: 2007, EMC Test Report (Exhibit 17B), characterizes the output beam profile and establishes that the light energy from the LEDs is delivered and concentrated in the desired target location.
- IEC 62471 SGS 04-2014, Photobiological Safety of lamps and lamp systems, (Exhibit 17C) was conducted in regard to power and performance of the LEDs, power measurements to demonstrate that the LED output power, specifically that reaching the target site, is predictable.
- Device Life Report (Exhibit 16A) confirms proper performance to design specifications and assess the probability of system failure, the means by which system failure can be mitigated, and the means by which system failure is apparent to the user.
- Risk assessment (Exhibit 18B1-3), assess the failure modes and probabilities.

**11. Labeling**

Cellulize labeling has been included as Exhibit 15B. Likewise, the Cellulize User manual is included as Exhibit 67. IEC 60601-1, Medical electrical equipment (Exhibit 17A) among other things addresses the legibility of marking and durability of marking. All Cellulize labeling satisfies the requirements of 21 CFR 807.87(e) and includes the following elements:

- Descriptions of:
  - the device and all accessories
  - how the device interconnects with other components or accessories
  - all features, functions, output modalities, and specifications
  - all user-accessible controls
  - indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display output jack, etc.
  - illustrations of the device and accessories
- Directions for Use
- Indications for Use, including Contraindications
- Storage Conditions
- Warnings
- Precautions
  - Need for protective eye wear during use
  - Electrical Shock
  - Unintended Cell Damage
  - Use Error

**12. Electrical Shock and Basic Safety**

IEC 60601, Medical electrical equipment (Exhibit 17A), was conducted to show

Electrical and Mechanical Safety Performance, and IEC 60601-2-57, Medical electrical equipment (Exhibit 17D), was conducted for particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

**13. Unintended Cell Damage**

Bench Testing was conducted in IEC 62471 SGS 04-2014, Photobiological Safety of lamps and lamp systems (Exhibit 17C). Cellulize passes all applicable tests.

**14. Software Validation**

No Software.

**15. Clinical Testing**

A clinical study was conducted, and is submitted in support of the 510(k) submission. The study was a double-blind, placebo-controlled randomized evaluation of the effect of Cellulize for aesthetic use for the non-invasive reduction in fat layer for body contouring and reduction of cellulite. A total of 52 patients participated in the study (25 Active Cellulize, and 27 Placebo Control). Patients were all female with a median age of 42.5 years old with a range of patient ages from 18 years to 69 years old. Ethnic origin of the patients were represented from Asian, African American, Caucasian, Latino, and Pacific Islander. Cumulative circumferences of waist, hip, left and right thighs for each patient was calculated before and after treatment. Three main points were concluded as a result of the study:

1. Cellulize causes immediate inch loss in subjects after a regimen of six treatments of 32 minutes (8 minutes on each of four positions) compared to individuals subjected to a placebo device for an equivalent treatment. In a typical regimen, patients lost an average cumulative 2.67 inches of circumference compared to placebo average of 0.5 inch. This meets the anticipated primary outcome measure "Average Change in Inches of Total Circumference Measurements for effect of Cellulize, a LED 532nm green light low level laser system for aesthetic use for the non-invasive reduction in fat layer for body contouring from baseline measurements, and after treatment."
   Figure 1, below, shows the graphical summary of inch loss for patients in the Cellulize active group and the Placebo control group respectively. Table 1 give the mean values for both groups as well as standard deviation for the "after" measurements, as well as 7-day and 14-day follow ups relative to the "before" measurements for each patient.

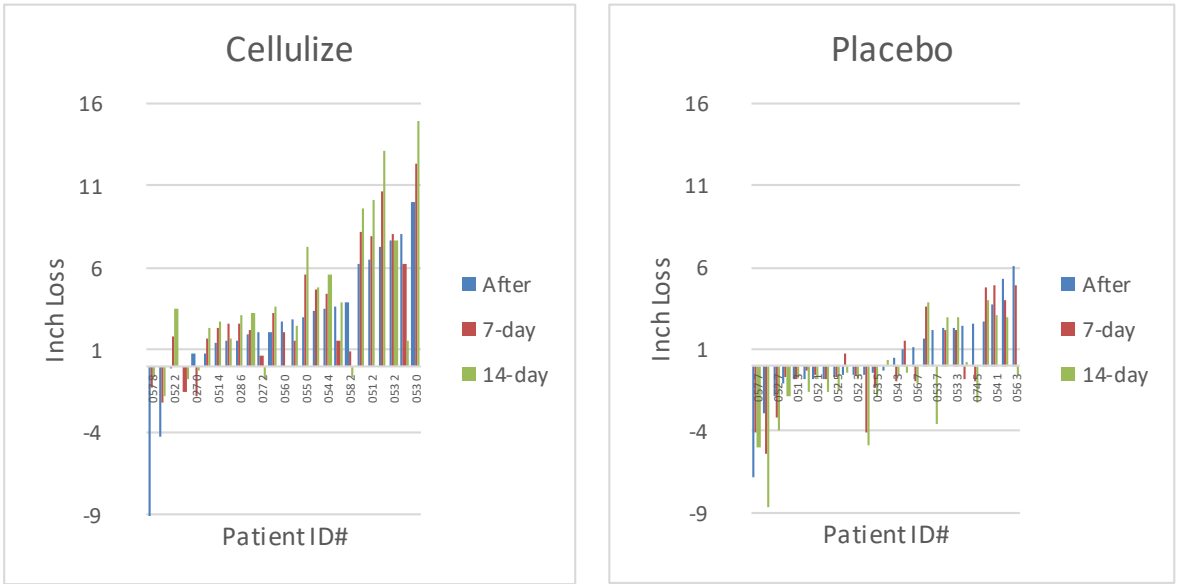


**Figure 7-1** – Patient inch loss/gain results comparison. Cellulize patients had significantly better cumulative inch loss than patients who received a placebo treatment using a sham device. The initial measurement after completing the treatment regimen (blue) is often followed by continued loss 7 days (red) and 14 days (yellow) after completing all treatment. Patients undergoing placebo procedure exhibited unpredictable gains or losses consistent with untreated patients, and the amplitude of the changes is smaller than patients treated with Cellulize.

| **Celluize Active Group** | **After** | **7-day** | **14-day** |
|---|---|---|---|
| Mean Cumulative Inch Loss (calculated from "before"): | 2.67 | 3.40 | 3.87 |
| Standard Deviation: | 4.04 | 3.81 | 4.45 |
| Min Inches Lost: | -9.88 | -2.25 | -1.88 |
| Max Inches Lost: | 10.00 | 12.38 | 15.00 |
| Additional Average Loss after time: | - | 0.73 | 0.47 |
| **Placebo Group** | **After** | **7-day** | **14-day** |
| Mean Cumulative Inch Loss (calculated from "before"): | 0.52 | 0.07 | -0.82 |
| Standard Deviation: | 2.61 | 2.72 | 2.95 |
| Min Inches Lost: | -6.88 | -5.38 | -8.63 |
| Max Inches Lost: | 6.13 | 4.88 | 4.00 |
| Additional Average Loss after time: | - | -0.45 | -0.89 |

**Table 7-1:** Inch Loss summary for Cellulize active Trial Participants and Placebo Trial Participants. The demonstrated inch loss, as well as continued effect, were greater and were generally desirable effect for the Cellulize Group. The placebo group had minimal effect and inch gain was more prevalent among participants.

2. While durability of effect is also impacted by extrinsic factors after treatment such as diet, it was demonstrated that subjects were more likely to show continued inch loss upon following up with each subject at 7 days and again at 14 days. In general, patients undergoing active Cellulize 532nm green light continued losing some inch with an average continued loss of an addition 1.20 inches for a total average inch loss of 3.87 inches where average placebo measurements after 14 days yielded a net gain (not a loss) of 0.875 inches. This implies that the green light treatment meets the expected primary outcome of demonstrated durability of effect after short-term follow up of 2-weeks.
3. Finally, the effect of Cellulize LED 532nm green light without any other intervention was measured for its effect on cellulite as part of the study. The Nurnberger-Muller Scale (NMS), a four-stage scale used as an industry standard to classify stage or degree of cellulite and to determine change in stage or degree of cellulite following treatment intervention, was used to ensure consistent evaluation standards. Results from the active device as well as placebo both showed that cellulite in general did not decrease on the back of thigh/buttocks for subjects after a single treatment of 532nm green light. This result failed to meet the anticipated primary outcome measure of decreasing appearance of cellulite as a measure of the Nurnberger-Muller Scale (NMS) from baseline to completion of treatment for the thigh/buttock area.

**16. Biocompatibility**

Non-Patient Contact

**17. Electromagnetic Compatibility**

IEC 60601-1-2 (Exhibit 17B)

**18. Use Error**

Addressed in Labeling (see above).

**19. Substantial Equivalence**

Cellulize, with its intended use, is equivalent to the predicate devices:

- Verju Laser, manufactured by Erchonia. The K130922 clearance is attached as Exhibit 14A.
- Photonica Professional, manufactured by Ward Photonics. The K160880 clearance is attached as Exhibit 14B.

Both of the predicate devices, as well as the candidate device, cause lipolysis, which reduces the circumferences as a result of exposure to 532 nm green light (or 635nm red light). Cellulize, is a circumference reducing LED light system using 532nm ± 3nm green light which is the same green light wavelength used by the VERJU.

The FDA product classification code, OLI, has a guidance document which is the special control for this product, *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use*. According to the guidance document, FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the low level laser system for aesthetic use. Cellulize complies with all of the standards outlined in the special controls consensus standards.

The principles of operation and base elements of the Cellulize device are very similar to the

Verju predicate device in the portability, and pole-mounted positioning over the patient; however, the Verju utilizes a different mechanism to achieve coverage of the treatment area with green light. The predicate Verju Laser utilizes six pin-point lasers positioned on articulating arms circumferentially positioned around the treatment area. The rotating lasers of the Verju project a concentrated high intensity green line over a small portion of the treatment area, and the system rotates to effectively cover a broad pattern, or to "scan" the treatment area for its coverage. Cellulize achieves treatment area coverage through a soft uniform bath of green light from an array of 150 diodes. Because "dosage" is a mechanism of energy, coverage and time, the Cellulize has matched the effectiveness of the predicate with LED green light to provide the same treatment. The table below details the similarities of the predicate to Cellulize. There are no differences between the subject device and the Verju Laser with respect to indications and intended use.

The Cellulize device is based upon the same design platform as the Photonica Professional predicate device in every aspect of the design except for the color of the LED array. Cellulize uses 532nm green light, and Photonicia Professional uses 635nm red light.

The Cellulize is substantially equivalent to the Verju Laser manufactured by Erchonia and subject of (K130922), as well as the Photonica Professional manufactured by Ward Photonics and subject of (K160880). Table 7-1 (below – refer to Section 13), gives the comparison between the two predicate devices and the candidate device.

## Table 7-2 – Comparison to legally marketed predicate device (ref: Section 13, Substantial Equivalence).

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| **510(k) Number** | **K130922** | **K160880** | **TBD** | No Difference | No Difference |
| **Product code** | **OLI** | **OLI** | **OLI** | | |
| **Regulation Number** | **878.5400** | **878.5400** | **878.5400** | | |
| **Clinical / Design Features** | | | | | |
| 1. Indications for Use | Device is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs. | Device is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. | Cellulize is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. | No difference except that Verju indication adds adjunct purpose of preparing individuals for liposuction procedures.<br><br>NOTE: Verju website does not mention adjunct purpose in their marketing. | No Difference |
| 2. Continuous or Pulsed | Continuous | Continuous | Continuous | No Difference | No Difference |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 3. Software Used? | Y – Verju has been marketed in the United States with various software operating systems, including some that incorporate pay-per-use features. All versions provide a 20-minute timer for the front and then 20 minutes for the back and operate using touch screen buttons. | N – Photonica is controlled by manual settings. | N – Cellulize is controlled by manual settings. | Cellulize is simpler without complex software to track usage and billing functions. | No difference |
| 4. Adjustable Light Positioning? | Y – articulated arms allow for many adjustments. | Y – articulated arm allows for many adjustments. | Y – articulated arm allows for many adjustments. | No Difference | No Difference |
| 5. Non-invasive? | Y | Y | Y | No Difference | No Difference |
| Safety Features | | | | | |
| 6. Patient Protective Eyewear Included? | N | Y – one box of 50 pairs of Kentek IPL SmartShield disposable eye protection are included | Y – one box of 50 pairs of Kentek IPL SmartShield disposable eye protection are included | Cellulize includes patient protective eyewear. | No Difference |
| 7. Operator Protective Eyewear Included? | Y – provides one pair of its private label branded operator protective eyewear | Y - one pair for the operator (Kentek IPLSAFE) | Y - one pair for the operator (Kentek IPLSAFE) | No Difference | No Difference |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 8. Power protection | Unknown | Isolation transformer separates facility power from the device. Power switch that cancels the treatment (lowest risk; key switch not required by IEEC standards). | Isolation transformer separates facility power from the device. Power switch that cancels the treatment (lowest risk; key switch not required by IEEC standards). | *Not available for comparison.* | No Difference |
| Light Emissions Specifications | | | | | |
| 9. Peak Wavelength | 532nm (visible green light spectrum) | 635nm ± 2nm (visible red light spectrum) | 532nm ± 3nm (visible green light spectrum) | No Difference | *Predicate Photonica uses red light.* |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 10. Total Power Output | 102 mW Using (6) 17mW Laser-Emitting Diodes (Lasers) | 240 W Using (150) 1600 mW Light-Emitting Diodes (LEDs) | 240 W Using (150) 1600 mW Light-Emitting Diodes (LEDs) | *The cumulative total power output of Cellulize with 150 LEDs is greater than the cumulative power output of Verju with six lasers.* | No Difference |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 11. Output intensity/ Irradiance ($mW/cm^2$) | 0.20 $mW/cm^2$ | 105 $mW/cm^2$ | 95.14 $mW/cm^2$ | *The Verju delivers all of its energy to a single point on the skin and uses scanning to distribute the power. At the point on the skin where the laser is focused, the laser is more powerful than the light from Cellulize, but because the Verju is continuously moving the active pinpoint with a scanning motion, the total photonic energy (luminous flux) delivered to the fat cells is much lower than Cellulize.* | Essentially the same |

| Manufacturer | Erchonia Corporation | Ward Photonics LLC | Ward Photonics LLC | *Significant Differences* *Verju vs Cellulize* | *Significant Differences* *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 12. Standard Treatment Time (minutes) | Two 15-minute exposures (front and back) at each 30-minute treatment session. The standard protocol is three sessions a week for two weeks as determined by the doctor. | Four 8-minute exposures (front, back, left, and right), 32-minute total per treatment session. The standard protocol is one session, taking the "before" and "after" measurements at the same office visit. | A treatment regimen consists of six sessions over a 2-week period. Each treatment is four 8-minute exposures (front, back, left, and right), 32-minute total per treatment session. | Cellulize achieves inch-loss results in one regimen of six 32-min. treatments. Verju standard protocol uses six 30-minute treatments to achieve similar results. | Cellulize achieves inch-loss results in one regimen of six 32-min. treatments. Photonica standard protocol measures treatment results after single visit. |
| 13. Maximum Coverage Area ($cm^2$) | 516 $cm^2$ maximum total coverage area with 6 scanning lasers operating 8" from the skin | 2294.0 $cm^2$ maximum total coverage area with 150 LEDs operating 6.8" from the skin | 2294.0 $cm^2$ maximum total coverage area with 150 LEDs operating 6.8" from the skin | Cellulize provides uniform illumination of 2294 $cm^2$ for the entire treatment time. Verju uses six laser heads scanning areas of 80 $cm^2$ for a total of 516 $cm^2$. | No difference |
| Overall Device Specifications | | | | | |
| 14. Unit Dimensions (H x W x D) | 170.2 cm x 78.74 cm x 154.9 cm | 183.2 cm x 62.2 cm x 61 cm | 183.2 cm x 62.2 cm x 61 cm | Both are similarly sized pole-mounted mobile systems with lights attached to arms and four casters for mobility. | No difference |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 15. Weight (kg) | 32 kg | 52 kg (with carton) | 52 kg (with carton) | The Cellulize includes the safety benefit of an isolation transformer that alone weighs 7.7 kg. It is unknown if the weight of the shipping carton is included in the value provided for the predicate. | No difference |
| 16. Power Source | 100-240V, 0.5-1.5A, 50/60 Hz | 100-120 VAC, 3A, 50/60 Hz | 100-120 VAC, 3A, 50/60 Hz | No difference | No difference |
| 17. Operating Temperature | Unknown, may be stored at up to 41°C | +5°C to 35°C | +5°C to 35°C | Similar, both comply with IEC 60601 safety standard which includes operating temperatures and humidity; intended for use in same environmental conditions. | No difference |
| 18. Operating Humidity | Unknown | 10% to 90% RH, non-condensing | 10% to 90% RH, non-condensing | | No difference |
| 19. Cooling Mechanism | None | Forced air ventilation | Forced air ventilation | No functional difference | No difference |
| 20. Expected Use Life | Unknown expected useful life. Comes with a two-year limited warranty. | At least 8,700 hours (16,312 of the 32-minute treatment sessions). Comes with a two-year warranty. | At least 8,700 hours (26,100 treatment sessions). Comes with a two-year warranty. | Similar. Both devices come with a two-year warranty. | No difference |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 21. Meets the OLI "Recognized Consensus Standard" | Yes | Yes | Yes | No difference | No difference |
| | | **Major Device Components** | | | |
| 22. Light Emitters | Verju has 532nm laser-emitting diodes on adjustable arms. | Cellulize has 635nm light-emitting diodes on an adjustable arm. | Cellulize has 532nm light-emitting diodes on an adjustable arm. | No difference | LEDs are red 635nm instead of 532nm |
| 23. Base Unit | Contains the Control Unit:<br>• LCD Display<br>• Keyboard for user input<br>• Control electronics<br>• Power supply with an interchangeable fuse | Contains the Control Console:<br>• Power indicator lamp<br>• Start button<br>• Timer switch<br>• Output connector to the LED Panel<br>• Power entry module with two user replaceable fuses<br>• Hours meter. | Contains the Control Console:<br>• Power indicator lamp<br>• Start button<br>• Timer switch<br>• Output connector to the LED Panel<br>• Power entry module with two user replaceable fuses<br>• Hours meter. | The predicate device is software driven and allows the user to select which lasers are active. Also used to track usage minutes and charge users according to Verju fee structure. The Cellulize uses mechanical timers. | No difference |
| 24. Mobile Cart | Y- mobile cart mounted system. | Y- mobile cart mounted system. | Y- mobile cart mounted system. | No difference | No difference |
| 25. Arms | Y - A folding arm system attaches the control unit to the laser heads. | Y – A fully articulating arm attaches to the mobile pole cart and the LED Panel. | Y – A fully articulating arm attaches to the mobile pole cart and the LED Panel. | Essentially no difference | No difference |

| **Manufacturer** | **Erchonia Corporation** | **Ward Photonics LLC** | **Ward Photonics LLC** | ***Significant Differences*** *Verju vs Cellulize* | ***Significant Differences*** *Photonica vs Cellulize* |
|---|---|---|---|---|---|
| **Trade Name** | **Predicate** **Verju Laser** | **Predicate** **Photonica Professional** | **New Device** **Cellulize** | | |
| 26. Isolation Transformer | Unknown | Y - A hospital-approved isolation transformer to provide additional protection to the patient from touch voltage -- reducing the maximum touch voltage by 94%, from 0.8v to 0.046v. | Y - A hospital-approved isolation transformer to provide additional protection to the patient from touch voltage -- reducing the maximum touch voltage by 94%, from 0.8v to 0.046v. | *Unable to determine* | No difference |

## Table 7-3 – Comparison to legally marketed predicate massager device (ref: Section 13, Substantial Equivalence).

| **Manufacturer** | **Erchonia Corporation** | **Pado, Inc.** | ***Significant Differences*** ***Percussor vs PureWave*** |
|---|---|---|---|
| **Address** | **650 Atlantis Rd Melbourne, FL 32904** | **28340 Avenue Crocker Unit 100 Valencia, CA 91355** | |
| **Trade Name** | **Predicate** **Percussor Therapeutic Massager** | **New Device** **PureWave CM5** | |
| **510(k) Number** | **K130922** | **N/A** | No Difference. PureWave is Class I exempt device. Percussor was included in K130922 as a Class I companion device. |
| **Product code** | **LYG / ISA** | **LYG / ISA** | |
| **Regulation Number** | **890.5660** | **890.5660** | |
| 1. Indications for Use | The Massager component is indicated for the temporary reduction in the appearance of cellulite. | The Massager component is indicated for the temporary reduction in the appearance of cellulite. | No Difference |
| 2. Claims / Clinical Efficacy | Percussion massage therapy | Percussion massage therapy | No Difference |
| 3. | 6 to 60 percussions per second | | |
| 4. Battery Powered | NO. Power cord to wall-mounted power source. | 7.2V Lithium-ion 2200mA 18650 x 2 Cell | Percussor uses power cord. PureWave is cordless. |
| 5. Charge Time | N/A | 120 minutes | Percussor uses power cord. PureWave is cordless. |
| 6. Variable Speed Range | 1 rpm - 3,600 rpm | 1,500 rpm - 3,700 rpm | Essentially No Difference |

| **Manufacturer** | **Erchonia Corporation** | **Pado, Inc.** | ***Significant Differences*** ***Percussor vs PureWave*** |
|---|---|---|---|
| **Address** | **650 Atlantis Rd Melbourne, FL 32904** | **28340 Avenue Crocker Unit 100 Valencia, CA 91355** | |
| **Trade Name** | **Predicate** **Percussor Therapeutic Massager** | **New Device** **PureWave CM5** | |
| 7. Motor Voltage | 120V AC | 7.2V, DC | Percussor uses power cord. PureWave is cordless. |
| 8. Motor Max RPM | 3600 Hz | 3700 Hz | Nearly identical. PureWave slightly exceeds Percussor. |
| 9. Charger Input Voltage | 100-120Vac, 50/60Hz only | 100V-240V, 50/60Hz, 0.4 A Max | PureWave allows 100 to 240 V. Percussor is 100 to 120V only. |
| 10. Charger Output Voltage | N/A | 8.5V, DC, 1A | Percussor uses power cord. PureWave is cordless. |
| 11. Power Indicator | N/A | YES - Green when fully charged | Percussor uses power cord. PureWave is cordless. |
| 12. Product Warranty | 2 Year | 1 Year | Percussor warranty is longer. |
| 13. Multiple Attachment Tips | Two Tips: One cone head tip, and one flat pad tip. NOTE: optional attachments available, not included. | Three Tips: One cone head tip, one six-point tip, and one flat pad tip. | PureWave includes an additional style of tip for more functionality. |
| 14. Hand-held | YES | YES | No difference |
| 15. Software | NO | NO | No difference |

| **Manufacturer** | **Erchonia Corporation** | **Pado, Inc.** | ***Significant Differences*** ***Percussor vs PureWave*** |
|---|---|---|---|
| **Address** | **650 Atlantis Rd Melbourne, FL 32904** | **28340 Avenue Crocker Unit 100 Valencia, CA 91355** | |
| **Trade Name** | **Predicate** **Percussor Therapeutic Massager** | **New Device** **PureWave CM5** | |
| 16. General Controls | YES | YES | No difference |

**20. Non-Clinical Performance Data**

Cellulize has been tested for all designated tests (as applicable) given in the Guidance document: Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use (Document issued on: April 14, 2011). A detailed review of the performance and safety testing is given in Section 017_Performance Testing – Bench.

**21. Statement of Substantial Equivalence**

The Cellulize is substantially equivalent to the Verju Laser manufactured by Erchonia and subject of K130922 as a 532nm green light non-invasive solution for the reduction of circumference of hips, waist, and thighs. Cellulize is also substantially equivalent to the Photonica Professional manufactured by Ward Photonics and subject of K160880, as a medical device shown to meet all of the special controls outlined in *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use*.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for its intended use.