DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 23, 2016

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

Re: K160880
Trade/Device Name: Photonica Professional
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: August 5, 2016
Received: August 5, 2016

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. 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,

Binita S. Ashar -S

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)*
K160880

Device Name
Photonica Professional

Indications for Use *(Describe)*

Photonica Professional is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. Photonica Professional is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 - 510(k) Summary For

Photonica Professional

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**

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

3. **Date Prepared**

May 5, 2016

4. **Device Identification**

Trade/Proprietary Name:	PHOTONICA PROFESSIONAL
Common/Usual Name:	Fat Reducing Low Level Laser
Classification Name:	Low level laser system for aesthetic use
Classification Regulation:	878.5400 and 878.4810
Product Code:	Both OLI and GEX
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. **Legally Marketed Predicate Device(s)**

The Photonica Professional is substantially equivalent to the following predicate devices:

- ERCHONIA ML SCANNER (K082609)
  The Photonica Professional is substantially equivalent to the ERCHONIA ML SCANNER manufactured by Erchonia and subject of K082609 (DEN090008).
- PHOTONICA PROFESSIONAL (K150336)
  The Photonica Professional is substantially equivalent to itself, being previously cleared (GEX) for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

6. Device Description

The Photonica Professional ("Photonica") is a non-invasive red light system with a power output of 105mW/cm2, consisting of 150 light emitting diodes (LEDs) that emit visible light at nominal wavelength of 635nm ± 2nm (visible red light spectrum) and a spectral bandwidth of 10nm. Photonica Professional is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. Photonica Professional is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

Photonica Professional was previously cleared (K150336), as a Laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).

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. Treatment time is preset to 8 minutes for non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs, (or 20 minutes for treatment of superficial, benign vascular and pigmented lesions, prior clearance K150336) 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 126 J/cm^2. Photonica does not use any software.

7. Indication for Use Statement

Photonica Professional is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. Photonica Professional is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

NOTE: The Photonica Professional with 635nm ± 2nm (visible red light spectrum), laser surgical instrument for use in general and plastic surgery and in dermatology, uses the same red light mechanism for both indications.

8. Substantial Equivalence Discussion

The (OLI) intended use of this device is equivalent to the predicate device, ERCHONIA ML SCANNER manufactured by Erchonia. Both devices cause lipolysis, which reduces the size of subcutaneous fat acculations as a result of exposure to 635 nm red light. Photonica Professional, laser surgical instrument for use in general and plastic surgery and in dermatology, uses 635nm ± 2nm (visible red light spectrum) which is the same red light wavelength used by the ERCHONIA ML SCANNER.

The (GEX) intended use of this device is equivalent to itself as the predicate device, PHOTONICA PROFESSIONAL, manufactured by Ward Photonics. The only modification of the Photonica Professional is to enable the timer for either 8 minute operation (for OLI

procedures), or 20-minute operation (for GEX procedures). The PHOTONICA PROFESSIONAL timer was previously only capable of 20-minute operation. The device is unchanged in every other measure.

The predicate Photonica Professional had two timer delay relays set for 20 minutes while the subject version has one set for 8 minutes and one set for 20 minutes. There are no other differences in the equipment.

Safety considerations of the PHOTONICA PROFESSIONAL were demonstrated and cleared in prior clearance K150336 for treatment times of 20 minutes. The newly prescribed treatment time of 8 minutes for the OLI treatment of fat reduction of circumference of hips, waist, and thighs is 12 minutes less than already approved for GEX. Because the treatment time for the new OLI indication is less than the already-cleared GEX indication of 20 minutes, there are no new safety concerns with this device.

The principles of operation and base elements of the device are identical in every aspect to the previously cleared PHOTONICA PROFESSIONAL device, and very similar to the ERCHONIA ML SCANNER predicate device in the portability, and pole-mounted positioning over the patient; however, the ERCHONIA ML SCANNER utilizes a different mechanism to achieve coverage of the treatment area with red light. The predicate ERCHONIA ML SCANNER utilizes five pin-point lasers positioned on articulating arms circumferentially positioned around the treatment area. The rotating lasers of the ERCHONIA ML SCANNER project a concentrated high intensity red 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. Photonica professional achieves treatment area coverage through a soft uniform bath of red light from an array of 150 diodes. Because “dosage” is a mechanism of energy, coverage and time, the Photonica professional has matched the effectiveness of the predicate with a simpler, safer method of treatment. The predicate Zerona delivers 9,600.0 Lux Minutes over the course of treatment while the Photonica Professional delivered 10,035.2 Lux Minutes over the course of treatment. There are no differences between the subject device and the ERCHONIA ML SCANNER with respect to indications and intended use.

The Photonica Professional is substantially equivalent to the Zerona ML SCANNER manufactured by Erchonia and subject of K082609 (DEN090008). The Photonica Professional is also substantially equivalent to itself, PHOTONICA PROFESSIONAL (K150336), being previously cleared (GEX) for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

The predicate Photonica Professional has the indication for use: “Photonica Professional is indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions. “ The new part of the indications for use is, “Photonica Professional is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.”

9. Non-Clinical Performance Data

Photonica Professional 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.

10. Clinical Performance Data

A multi-site retrospective analysis has been performed on the records of 58 patients, which demonstrates the efficacy of the device using the patented UltraSlim Cold Light® protocol with an 8-minute exposure to the front of the body, 8 minutes to the left side, 8 minutes to the back, and 8 minutes to the right side, with a total of 32 minutes exposure time for each treatment session.

The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the United States of America to determine the combined circumferential reduction of the waist, hips, and thighs with a single 32-minute treatment session using the subject Photonica Professional product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this patented procedure and to compare the procedure's effectiveness with non-invasive fat reduction using the Zerona scanning low-level laser system by Erchonia Corp.

The studies also differ in that the Erchonia protocol was performed over a three-week period with six 40-minute treatments and with a robust protocol of dieting, exercise, abstinence from alcohol, and the taking daily of proprietary pills.

In order to assure a fair comparison of the measurements with the predicate's measurement schema, the measurements in this study were taken in exact accordance with the Zerona Male Measurement Guide, Female Measurement Guide, Male Measurement Form, and Female Measurement Form as were used in the clinical trials upon which the predicate's *de novo* application was approved. Those results were published in *Low-Level Laser Therapy as a Non-Invasive Approach for Body Contouring: A Randomized, Controlled Study", Lasers in Surgery and Medicine 41 (10): 799–809. doi:10.1002/lsm.20855, PMID 20014253.*

The same self-tensioning measuring tapes were used for both studies. As detailed in the Zerona measurement guides and forms, multiple circumferential measurements were recorded for each patient. The measurement reference points are described in the Zerona Male Measurements Guide as quoted here for five measurements:

Back	Circumference at level of nipples
Upper-Abdomen	Distance above umbilicus
Mid-Abdomen	2-3 inches above the umbilicus
Flanks	Circumference around the "love handles"
Lower-Abdomen	Distance from umbilicus

The measurement reference points are described in the Zerona Female Measurements Guide as quoted here for six measurements:

Back	Circumference where fat is under bra and note distance in inches above the umbilicus
Waist	2-3 inches above umbilicus (note distance)
Mid-Abdomen	2-3 inches below umbilicus (note distance)
Hips	Note distance below umbilicus
Thighs (right and left)	Greatest circumference, then note distance from top of kneecap

The results of the retrospective analysis are summarized in the three-page table below:

Title of Study:	A Retrospective Analysis of the Effects of Red Light Therapy on Body Contouring
Study Objective:	The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the United States of America to determine the combined circumferential reduction of the waist, hips, and thighs with a single 32-minute treatment session using the subject Photonica Professional product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this patented procedure and to compare the procedure's effectiveness with non-invasive fat reduction using the Zerona scanning low-level laser system by Erchonia Corp.
Number of Sites:	2
Enrollment Size:	58
Patient Population	For the study, 46 of the patients are female (79%) and 12 are male (21%). Females ranged in age from 18 to 74, with an average age of 42.2 years. Males ranged in age from 25 to 67, with an average age 43.3 years. Overall, patients ranged in age from 18 to 74, with an average age 43.3 years.
Study Design	Photonica Professional was positioned 17cm from the skin with four 8-minute exposures. For males, the emitter was positioned: • Front: Over the chest and abdomen, extending 23" toward the superpublic area. • Back: Starting at the top of buttocks, extending 23 inches towards the upper back. • Left: From the left hip area, extending 23 inches towards the left underarm area. • Right: From the right hip area, extending 23 inches towards the right underarm area. For females, the emitter was positioned: • Front: From below the bra and extending 23" to include the top of the thighs. • Back: Covering the "back" measurement area and extending

<table>
<tr><td></td><td>23” to include the top of the thighs.
• Left: With the pelvis tilted back about 45° and the right knee extended in front of the left knee, the light is aligned to cover the left “love handle”, the outside of the left thigh, and the inside of the right thigh, along with the lower abdomen.
• Right: With the pelvis tilted back about 45° and the left knee extended in front of the right knee, the light is aligned to cover the right “love handle”, the outside of the right thigh, and the inside of the left thigh, along with the lower abdomen.</td></tr>
<tr><td>Measurements and Timing</td><td>Measurements were taken immediately before and after the 32-minutes treatment using a self-tensioning measuring tape, measurement forms, and instructions (Measurements Guides) exactly as used in the clinical trials for the predicate Zerona.

Since measurements were taken immediately before and after the treatment, the observed results are therefore immediate.</td></tr>
<tr><td>Treatment</td><td>The treatments consists of four 8-minute exposures with the 635nm light positioned 17cm from the skin.

Photonica Professional outputs 105 mW/cm^2, delivering 50.4 J/cm^2 to the skin, delivering 313.6 lx to the subcutaneous fat, and delivering a total luminous flux dose per treatment of 10,035.2 Lux Minutes.</td></tr>
<tr><td>Results</td><td>Inch loss by gender is:

<table>
<tr><th>Gender</th><th>Patients</th><th>Age</th><th>Inch Loss</th><th>Std. Dev.</th><th>Volume Lost (ml)</th></tr>
<tr><td>Males</td><td>12</td><td>43.3</td><td>3 1/8</td><td>7/8</td><td>1,568.8</td></tr>
<tr><td>Females</td><td>49</td><td>42.2</td><td>3 4/8</td><td>1 5/8</td><td>1,583.2</td></tr>
<tr><td>Total</td><td>58</td><td>42.4</td><td>3 4/8</td><td>1 4/8</td><td>1,580.2</td></tr>
</table>

Inch loss by treatment site is:

<table>
<tr><th>Site</th><th>Patients</th><th>Age</th><th>Inch Loss</th><th>Std. Dev.</th><th>Volume Lost (ml)</th></tr>
<tr><td>A</td><td>29</td><td>43.3</td><td>3 1/8</td><td>7/8</td><td>1,415.2</td></tr>
<tr><td>B</td><td>29</td><td>41.6</td><td>3 6/8</td><td>1 6/8</td><td>1,745.2</td></tr>
<tr><td>Total</td><td>58</td><td>41.9</td><td>3 4/8</td><td>1 4/8</td><td>1,580.2</td></tr>
</table>

Patients lost a minimum of 1 5/8” and 716.6ml. The maximum lost is 10” and 4,608.2ml.

For males, inch loss is computed by adding the inch loss measurements for back, upper-abdomen, mid-abdomen, flanks, and lower-abdomen.

For females, inch loss is computed by adding the inch loss measurements for back, waist, mid-abdomen, hips, and thighs.</td></tr>
</table>

	Volume for the 23" vertical treatment "cylinder" (based on the size of the light illumination from the device) is computed based on the 23" height multiplied by the average area of the five slices of the male abdomen or the four slices of the female abdomen. Volume lost is computed as the change in volume as computed from the average before and average after abdominal measurements, specifically: Volume Lost = $\mu[\pi * R_{Before}^2] * 23" - \mu[\pi * R_{After}^2] * 23"$).
Adverse Events	There were no device-related adverse events.
Substantially Equivalent to Predicate	Photonica Professional™ achieved an average combined circumferential reduction of the waist, hips, and thighs of 3.5" at one visit using the same measurements schema as in the Zerona® study which found an average loss of 3.6" with six 40-minute treatments and seven office visits over three weeks with dieting, exercise, and daily pills containing Erchonia's proprietary formula.

Further, 100% of patients had clinically significant results at one visit with Photonica Professional, considering that all patients lost at least 1 5/8" and at least 716.6ml of fat with one treatment. By comparison, traditional liposuction is limited to removal of no more than 500ml of fat at one surgery, due to the attendant trauma and potential side-effects.

NOTE: While treatment with Photonica Professional immediately reduces the size of subcutaneous fat accumulations exposed to the lights, treatments do not prevent the patient from subsequently gaining weight or increasing the size of the fat accumulations. The durability of the treatment has not been studied or established in follow-up clinical trials with a sufficiently statistically significant sample.

11. Statement of Substantial Equivalence

The Photonica Professional is substantially equivalent to the Zerona ML SCANNER manufactured by Erchonia and subject of K082609 (DEN090008). The Photonica Professional is also substantially equivalent to itself, PHOTONICA PROFESSIONAL (K150336), being previously cleared (GEX) for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

The results of non-clinical performance data confirm that the Photonica Professional delivers substantially equivalent Total Treatment Dose (Luminous Flux Minutes) of 635nm light to the subcutaneous fat cells in 32 minutes at one visit rather than in 240 minutes at six treatment visits.

The results of clinical testing confirm that the Photonica Professional achieves circumferential reduction substantially equivalent to the Zerona, but in 32 minutes rather than three weeks.

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.