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

February 24, 2015

Ward Photonics LLC
% Ms. Diane Sudduth
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K150336
Trade/Device Name: Photonica Professional
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 6, 2015
Received: February 10, 2015

Dear Ms. Sudduth:

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" (21CFR 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,

Jennifer R. Stevenson -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)*

Device Name
Photonica Professional

Indications for Use *(Describe)*
Photonica Professional is 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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

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510(k) Summary K150336

For

Photonica Professional

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

January 6, 2015

4. Device Identification

Trade/Proprietary Name:	PHOTONICA PROFESSIONAL
Common/Usual Name:	Laser Powered Surgical Equipment
Classification Name:	Powered Laser Surgical Instrument
Classification Regulation:	878.4810
Product Code:	GEX
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

The Photonica Professional is substantially equivalent to the Omnilux revive™ manufactured by Photo Therapeutics Ltd and subject of K030426.

6. Device Description

The Photonica Professional ("Photonica") is a non-invasive red light system with a power output of 105mW/cm^2, 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, for treatment of superficial, benign vascular and pigmented lesions. The components 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), 20 minute timer, on/off switch, and a hospital-grade power cable. The articulated arm allows the light fixture to be positioned in a wide variety of 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 20 minutes 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 is intended for use in dermatology for treatment of superficial, benign vascular and pigmented lesions.

8. Substantial Equivalence Discussion

The intended use and technological characteristics of this device are identical to the predicate device. The principles of operation and base elements of the device are similar to the predicate device and do not raise different questions of safety and effectiveness than the predicate. See Section 12 – Substantial Equivalence Discussion.

Table 5A – Comparison of Characteristics

Manufacturer	**Photo Therapeutics Ltd**	**Ward Photonics, LLC**	**Significant Differences**
Trade Name	**Predicate** **Omnliux revive™**	**New Device** **Photonica Professional**	
510(k) Number	K030426	Not assigned	N/A
Product code	GEX	GEX	N/A
Regulation Number	878.4810	878.4810	N/A
Clinical / Design Features			
Indications for Use	In dermatology for treatment of superficial, benign vascular, and pigmented lesions.	In dermatology for treatment of superficial, benign vascular, and pigmented lesions.	None
General Design Feature	One LED array	One LED array	None
Adjustable LED Panel?	Y	Y – articulated arm allows for many adjustments.	None
Non-invasive?	Y	Y	None

Manufacturer	**Photo Therapeutics Ltd**	**Ward Photonics, LLC**	**Significant Differences**
Trade Name	**Predicate** **Omnliux revive™**	**New Device** **Photonica Professional**	
Protective Eyewear Included?	Y – one pair for the patient	Y – one pair for the patient; one pair for the operator	Photonica provides operator eyewear for added safety
Head / Lamp Specifications			
Wavelength	633±6nm (visible red light spectrum)	635nm± 2nm (visible red light spectrum)	Similar, ± variance is in alignment with the range of both devices
Bandwidth	20nm ± 3nm	10nm	Photonica has a narrower specification than the predicate
Total LED Power Output	44.7 W ± 5W	240 W	Photonica has more total power, but power is distributed over a larger area such that the output internally and dosage is the same as Omnilux.
Output intensity/ Irradiance (mW/cm^2)	105 mW/cm^2	105 mW/cm^2	None
Recommended Treatment Time (minutes)	20 minutes	20 minute	None
Standard Energy Does (J/cm^2)	126 J/cm^2	126 J/cm^2	None
Typical Coverage Area (cm^2)	803 cm^2	2294 cm^2	Similar, spot size is dependent upon number of LEDs and array configuration.
Head / Lamp Dimensions (cm)	32 cm x 28 cm	28.8 cm x 44.5 cm	No functional difference
Dimensions of Active LED Area (cm)	15 cm x 28 cm	22 cm x 38 cm	No functional difference
Overall Device Specifications			
Unit Dimensions (H x W x D)	35.5 cm x 17.8 cm x 48 cm	183.2 cm x 62.2 cm x 61 cm	Omnilux is a tabletop device; the Photonica is a free standing unit on a mobile cart.
Weight (kg)	12 kg	52 kg (with carton)	Photonica includes safety benefit of the isolation transformer which weighs 7.7 kg; size of the Photonica device is larger than the Omnilux.

Manufacturer	Photo Therapeutics Ltd	Ward Photonics, LLC	Significant Differences
Trade Name	**Predicate** **Omnliux revive™**	**New Device** **Photonica Professional**	
Electrical Base	120 VAC, 8.0 amps, 50/60 Hz	100-120 VAC, 3 amps, 50/60 Hz	Functionally the same
Power source	90V -250V, 8A, 50/60 Hz	100-120 VAC, 3A, 50/60 Hz	Functionally the same
Operating Temperature	10°C to 30°C	+5°C to 35°C	Similar, both comply with IEC 60601-1 safety standard which includes operating temperatures and humidity; both devices are intended for use in the same environmental conditions.
Operating Humidity	30% to 85% (Relative)	10% to 90% RH, non-condensing	
Cooling Mechanism	Forced air ventilation	Forced air ventilation	None
Safety features	Unknown	Isolation transformer separates facility power from the device. Power switch cancels the treatment (lowest risk; key switch not required by IEEC standards).	Not available for comparison

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness, Photonica was tested and shown to be in compliance with IEC 62471 for Photobiological Safety of Lamps and Lamp Systems. Testing to the third edition of IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-57 has been conducted and demonstrated that the Photonica device performs according to specifications and functions as intended.

Based upon an analysis of the overall performance characteristics for the device, Ward Photonics (hereafter "Ward") believes that Photonica Professional is substantially equivalent to the predicate device. In addition, Ward concludes that the Photonica is substantially equivalent with respect to safety, effectiveness and functionality to the Omnilux revive with the exception of the Photonica does not contain software.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device.

11. Statement of Substantial Equivalence

The Photonica device has the same intended use and technological characteristics as the predicate device, Omnilux revive™, manufactured by Photo Therapeutics Ltd.

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.