December 18, 2020

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

Re: K202361
Trade/Device Name: UltraSlim Digital, UltraSmooth Digital
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
878.5650
Regulatory Class: Class II
Product Code: OLI, GEX
Dated: September 23, 2020
Received: September 24, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202361

Device Name
UltraSlim® Digital and
UltraSmooth® Digital

Indications for Use *(Describe)*

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

UltraSmooth DIGITAL 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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510(k) Summary For

UltraSlim® Digital and UltraSmooth® Digital

1. **Submission Sponsor**

Ward Photonics LLC
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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
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Telephone: (801) 633-9660
Contact: Jeff Brown, Managing Partner
Email: jeffbrown144@gmail.com

3. **Date Prepared**

August 18, 2020

4. **Device Identification**

	Predicate		**Subject**	
Trade/Proprietary Name:	**Photonica Professional** OLI (K160880) GEX (K150336)	**Cellullize** OLI (K180338)	**UltraSlim® Digital**	**UltraSmooth® Digital**
Common/Usual Name:	Fat Reducing Low Level Laser	Fat Reducing Low Level Laser	Fat Reducing Low Level Laser	Fat Reducing Low Level Laser
Classification Name:	Low level laser system for aesthetic use	Low level laser system for aesthetic use	Low level laser system for aesthetic use	Low level laser system for aesthetic use
Classification Regulation:	878.5400 (OLI) 878.4810 (GEX)	878.5400 (OLI)	878.5400 (OLI) 878.4810 (GEX)	878.5400 (OLI)
Device Class:	Class II	Class II	Class II	Class II
Classification Panel:	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery

5. Indications for Use

The indications for use did not change as a result of the device design changes. The stated indications for use are as follows:

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

6. Electromagnetic Disturbances and Wireless Compliance

Testing was conducted by SGS in Suwannee, Georgia, to ensure that the addition of a 4-Channel WiFi Relay Switch did not produce electromagnetic disturbances in medical equipment as designated in IEC 60601-1-2:2014, and to ensure wireless compliance to RF emissions in the frequency range 9 kHz to 231 GHz as required in ANSI C63.10: 2013 (FCC Part 15 Subpart C, § 15.247). All test results were compliant.

7. Legally Marketed Predicate Device(s)

The UltraSlim® Digital is substantially equivalent to its legally marketed predicate, Photonica Professional (K160880 & K150336), and UltraSmooth® Digital is substantially equivalent to its legally marketed predicate, Cellulize (K180338).

8. Device Description

UltraSlim® Digital and UltraSmooth® Digital are LED light therapy devices. The UltraSlim Digital uses 625nm red light (UltraSlim Digital), and the UltraSmooth Digital uses 532nm green light (UltraSmooth Digitial). The devices are generally described as pole-mounted and free-standing on a rolling base as shown in the figures below.

Note that the commercial names of the units were changed from Photonica Professional and Cellulize, to UltraSlim and UltraSmooth, respectively for marketing purposes, and the listings for each device were subsequently updated.

Both devices, UltraSlim® Digital and UltraSmooth® Digital, continue to share the same design platform, and only differ in the color of the LED light array. The associated branding/names, warning labels, and differences due to their respective indications for use will remain the same as previously cleared, and do not change as a result of this proposed controller change.

Design Features / Similarities

All design and manufacturing parameters are very similar in both devices including the power supply, drivers, internal components, physical form, and control. The devices consist of a main control unit, LED panel, and cable connections. The main control unit contains the main input, fuses, power supply, control circuits, and Minutes selector switch. The power switch has a failsafe system that ensures the voltage from a wall socket can never come in contact with the user. A hospital-approved isolation transformer is mounted on the base of the medical pole cart whose low center of gravity also supports the main control unit and the light fixture from tipping. The console is mounted to the pole with an articulated arm. Treatment time is

selected from pre-determined options programmed into the digital timer relay that do not allow the user to vary treatment times. System operation is preset. Both units operate at a frequency of 50Hz – 60Hz and a total power output of 300 W.

Both devices have already been cleared for their two treatment time options: 8-minutes and 20-minutes which does not change. The use of 8-minute intervals is typically used during fat loss in order to expose the patient for 8-minute intervals on different areas of the skin while the 20-minute treatment option is for skin treatments in a single sustained area. The prior design included an internal timer pre-set to 8 and 20 minutes. The user selected the desired treatment time using a toggle switch located on the control cabinet, and there were no options for the user to alter the pre-set treatment times.

Design Change Details

A design change was implemented, in an identical way, in the control of both devices that changes the unit from manual control to WiFi control. In general terms, the design change effectively replaces the electronic relay from the old design with a WiFi relay switch that is activated via WiFi from a mobile, desktop, tablet, or laptop device.

The new control design centers around replacing the manual time interval select and start button with a 4-Channel WiFi Relay Switch. Initiating a start sequence of the unit will be performed via internet control using a Relay Switch that receives its instructions from the user

through WiFi control. Users continue to be restricted to the treatment time options of 8 and 20 minutes in the web app, and are able to start the device from the WiFi control.

The push button momentary start switch is removed in the new design. Users only have the ability to start the device by way of WiFi control.

The devices with the new design change do not contain any software. However, a web app accessible through the internet allows users to log in, select treatment time options of 8 minutes or 20 minutes, and to initiate treatment. The built-in timer control via the 4-Channel WiFi Relay Switch automatically stops the treatment at the end of the approved treatment time based upon the input received from the user.

Each device has a unique local IP address that is associated with its assigned router. Each router has its own unique client's ISP-assigned Static IP and may be controlled by WiFi from any phone, tablet, or computer with Internet access.

All of the specific component/control changes include:

- Inside the console, the two existing timer delay relays and sockets are replaced with one timer delay relay board that has four relays and WiFi.
- A failsafe shut-off relay on the incoming 120VAC breaks the circuit to the LEDs which creates heat if the cooling fans lose their 12VDC power. The failsafe shut-off relay prevents any possibility of overheating if the three cooling fans should ever lose 12VDC power.
- Instead of locating a 12VDC power supply in the emitter, 12VDC is received from an existing power supply in the console, along with 120VAC and ground. Accordingly, the existing PowerCon, three-conductor cable between console and emitter, and cable gland on the emitter are replaced with a four-conductor cable and 4-pin Amphenol connectors on the console and emitter.
- On the console, the look of the unit has been altered by relocating the Power and Active LEDs. A "Power" LED is added to indicate that the unit is powered. A "Ready" LED is added to indicate that WiFi is connected and communicating properly with its router, and a "Active" LED illuminates when a treatment is active. The Start and Time switches are omitted.
- There is no change in size or shape of the device and no change to the treatments, output LEDs, power, brightness, timer durations, pole cart, emitter steel case, brackets, arm, warning labels, or isolation transformer. The weight difference between the current versions and the Digital versions is less than one pound.
- Treatment time is dictated to the controller from the web app software instead of an externally-mounted toggle switch.
- Treatment light is turned on by the WiFi-enabled relay instead of using a momentary start button. The relay turns the treatment light off at end of set time.

The scope of the changes to the equipment design have not impacted any of the performance aspects of the devices including:

- Indication for Use - unchanged.

- Light color/wavelength
- Treatment times
- Electrical Shock and Basic Safety
- Photobiological Safety
- Risk of Ocular Injury

The new design was bench tested by SGS in Suwannee, Georgia, for any impact from changing to the new WiFi control to ensure compliance to approved consensus standards. Test results show that the devices are in compliance.

- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI C63.10: 2013 (FCC Part 15 Subpart C, § 15.247) American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices

9. Labeling

All labeling of the device remains the same with the exception of the user manuals which have been updated in compliance with IEC/EN 60601-1-2:2014, Clause 5 Identification, Marking and Documents. The user manuals have also been revised to include instructions pertinent to the WiFi control of the device. The new marketed name "UltraSlim Digital" and "UltraSmooth Digital" respectively, adds the new word, "Digital" to the trade name to differentiate it from the prior design. All product labeling continues to satisfy the requirements of 21 CFR 807.87(e).

10. Electrical Shock and Basic Safety

Compliance to IEC 60601-2-57, Medical electrical equipment for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use remains unchanged as a result of design changes.

11. Photobiological Safety

The photobiological safety of the devices remains unchanged from the previously cleared design.

12. Software Validation

No software resides on the device; however, a web app is used to control the WiFi switch turning the unit on via WiFi control as described above. After activating the treatment, the unit runs its designated time using the timer control of the relay – same as before.

The software control of the web app to log in and initiate treatments was validated.

13. Cybersecurity

A risk-based cybersecurity safety evaluation was performed as part of the new design evaluation. This information is used to support the evaluation of the safety and effectiveness of this WiFi-enabled device.

The software level of concern is described as "Minor" because any possible failures or latent design flaws are unlikely to cause any injury to the patient or operator.

The Cybersecurity Risk Classification Level of Concern is classified as Tier 2 "Standard Cybersecurity Risk." The device is considered Tier 2 "Standard Cybersecurity Risk" devices because one of the criteria for Tier 1 classification is not met even though it is capable of connecting to a network / internet. Ward Photonics has determined that a cybersecurity incident affecting the device could not directly result in patient harm to even one or multiple patients.

14. Clinical Testing

No new Clinical Testing was conducted.

15. Biocompatibility

Non-Patient Contact

16. Electromagnetic Compatibility

IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

17. Substantial Equivalence

The UltraSlim® Digital is substantially equivalent to its legally marketed predicate, Photonica Professional (K160880 & K150336), and UltraSmooth® Digital is substantially equivalent to its legally marketed predicate, Cellulize (K180338).

Under the scope of the proposed design change, the devices continue to be in conformity to an FDA guidance document 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.

18. Non-Clinical Performance Data

UltraSlim® Digital and UltraSmooth® Digital have been tested and are in compliance with all applicable standards given in the Guidance document: Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use (Document issued on: April 14, 2011). This includes 12-242 IEC 60601-2-57 Edition 1.0 2011-01 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

19. Clinical Performance Data

The submission does not contain clinical performance data.

20. Statement of Substantial Equivalence

UltraSlim® Digital and UltraSmooth® Digital are substantially equivalent to the predicate devices already in commercial distribution by Ward Photonics. The comparison of the devices supports the claim of substantial equivalence to the predicate devices and that the systems continue to be safe and effective for their intended uses after undergoing a design change to the control mechanism of the device design.

The Substantial Equivalence Discussion also includes a design control verification

summary based upon risks identified as a result of the design change, and indicates that the UltraSlim® Digital (635nm) and UltraSmooth® Digital (532nm) are compliant to recognized consensus standards, or that other elements of risk have been mitigated appropriately, along with the verification of such activities.