November 10, 2022

Tentech Co. Ltd.
Lee Dong Gun
Quality Assurance Manager
3F Hyungkyung Building, 611, Seolleung-ro
Gangnam-gu, Seoul 06103
Korea, South

Re: K220794
Trade/Device Name: 10PL
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: ONF
Dated: September 29, 2022
Received: October 11, 2022

Dear Lee Dong Gun:

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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K220794

Device Name
10PL

Indications for Use *(Describe)*

The Photo therapy unit (model: 10PL) is intended for use in surgical and aesthetic applications in dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.

Wavelengths	Conditions
415nm - 950nm	Melasma
570nm - 950nm	Melasma, Rosacea
590nm - 950nm	Rosacea, Port wine stains

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.

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3F, Hyunkyung Building, 611, Seolleung-ro, Gangnam-gu, Seoul, 06103, Republic of Korea
TEL: +82 02 6954 2203 FAX: +82 02 3444 4999

510(k) Summary

K220794

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

November 08, 2022

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Tentech Co., Ltd.
- Address: 3F, Hyunkyung Building, 611, Seolleung-ro, Gangnam-gu, Seoul, 06103, Republic of Korea
- Contact Name: Dong Gun, Lee
- Telephone No.: 82-(0)2-6954-2203
- Fax No.: 82-(0)2-3444-4999
- Email Address: tentech.rnd@gmail.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Photo therapy unit
Trade name: 10PL

Classification Description	21 CFR Section	Product Code
Powered Light based Non-Laser Surgical Instrument With Thermal Effect	878.4810	ONF

As stated in 21 CFR, parts 878.4810, this generic types of devices has been classified as Class II.

3F, Hyunkyung Building, 611, Seolleung-ro, Gangnam-gu, Seoul, 06103, Republic of Korea
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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device 1

- 510(k) Number: K102857
- Applicant: Ahwon Medi Instrument.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: R2PL System

Predicate device 2

- 510(k) Number: K181868
- Applicant: IDS, Ltd.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: SHINY RPL System

Predicate device 3

- 510(k) Number: K192539
- Applicant: El. EN. Electronic Engineering SPA
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: Deka Luxea “LAZUR Pulsed Light handpiece”

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5. Description of the Device [21 CFR 807.92(a)(4)]

When the key switch is turned on for the first time [ON], the power supply to remove noise by receiving general power (AC120V) from the block diagram is applied to the SMPS to obtain the power supply and DC12V, the power used for the motor pump and cooling fan and the main control board.

POWER SUPPLY is a device that charges DC high voltage using SMPS by receiving stable power, and generates maximum DC600V±10% to charge the CAPACITOR.

When the charged DC voltage is applied to the xenon lamp of the handpiece, a desired wavelength is selected among the emitted rays, and the push button switch is pressed the rays are irradiated.

In order to use the light irradiator safely, a motor pump and a cooling fan are used to circulate the coolant to cool the xenon lamp and operate the thermoelectric module in the handpiece to keep the folter set to the desired temperature.

Set the output intensity and operation mode on the touch screen operation panel of the LCD monitor of the main control board, and select the READY button to turn on the xenon lamp, and press the push button switch to irradiate the light.

10PL is IPL device of Tentech Co., Ltd. that has technical advantages which adopted the rotary filter which can change wavelength band by rotating a revolver without replacing handpieces or filters unlike the existing IPL (Intense Pulsed Light)

6. Indications for Use [21 CFR 807.92(a)(5)]

The Photo therapy unit (model: 10PL) is intended for use in surgical and aesthetic applications in dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.

Wavelengths	Conditions
415 - 950nm	Melasma
570 - 950nm	Melasma, Rosacea
590 - 950nm	Rosacea, Port wine stains

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7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the 10PL and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

Table 1. General Comparison of Photo therapy unit

<table>
<tr><th></th><th>Proposed Device</th><th>Predicate Device #1</th><th>Predicate Device #2</th><th>SE decision</th></tr>
<tr><td>K Number</td><td>K220794</td><td>K102857</td><td>K181868</td><td>-</td></tr>
<tr><td>Manufacturer</td><td>Tentech Co., Ltd.</td><td>Ahwon medi Instrument.</td><td>IDS, Ltd.</td><td>-</td></tr>
<tr><td>Trade Name</td><td>Photo therapy unit</td><td>R2PL™ System</td><td>SHINY RPL System</td><td>-</td></tr>
<tr><td>Indications for Use</td><td>The Photo therapy unit (model: 10PL) is intended for use in surgical and aesthetic applications in dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.
<table>
<tr><th>Wavelength</th><th>Condition</th></tr>
<tr><td>415-950 nm</td><td>Melasma</td></tr>
<tr><td>570-950 nm</td><td>Melasma, Rosacea</td></tr>
<tr><td>590-950 nm</td><td>Rosacea, Port wine stains</td></tr>
</table></td><td>The Ahwon R2PL system intended use for in Surgical, Asthetic and Cosmetic Application in Dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.
<table>
<tr><th>Wavelength</th><th>Condition</th></tr>
<tr><td>415-950 nm</td><td>Acne, Vulgaris</td></tr>
<tr><td>560-950 nm</td><td>Melasma, Ephelides</td></tr>
<tr><td>590-950 nm</td><td>Port wine stains, Rosacea</td></tr>
<tr><td>640-1200nm</td><td>Melasma</td></tr>
<tr><td>695-1200nm</td><td>Hair reduction.Removal Vascular lesions</td></tr>
</table></td><td>The IDS SHINY IPL system is intended for use in Surgical, Aesthetic and Cosmetic applications in Dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.
<table>
<tr><th>Wavelength</th><th>Condition</th></tr>
<tr><td>415-950 nm</td><td>Acne, Vulgaris</td></tr>
<tr><td>560-950 nm</td><td>Melasma, Ephelides</td></tr>
<tr><td>640-950 nm</td><td>Acne, Hair Reduction</td></tr>
<tr><td>640-1200nm</td><td>Hair Reduction</td></tr>
<tr><td>695-1200nm</td><td>Hair Reduction</td></tr>
<tr><td>755-1200nm</td><td>Hair Reduction</td></tr>
</table></td><td></td></tr>
<tr><td>Energy Density</td><td>5-35J/cm^2</td><td>5-40J/cm2</td><td>5-40J/cm2</td><td>Different</td></tr>
<tr><td colspan="5">Different – Energy Density
The Energy density for proposed device is different from the predicate devices. However, the Energy Density of the proposed Photo therapy unit is covered by the range of the Energy Density of the predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness</td></tr>
<tr><td>Wavelength</td><td>415-950 nm
570-950 nm
590-950 nm</td><td>415nm – 950nm
560nm – 950nm
590nm – 1200nm
640nm – 1200nm
695nm – 1200nm</td><td>415nm – 950nm
560nm – 950nm
640nm – 950nm
640nm – 1200nm
695nm – 1200nm
725nm – 1200nm</td><td>Different</td></tr>
</table>

	Proposed Device	Predicate Device #1	Predicate Device #2	SE decision
Different – Wavelength The Wavelength for proposed device is different from the predicate devices. However, the Wavelength of the proposed Photo therapy unit is covered by the range of the Wavelength of the predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness The 415-950 nm was compared with the predicate device in the LAZUR Pulsed Light handpiece in Table 2.				
Pulse width	2.0-35.0ms(On Time) 3.0-60.0ms(Off Time)			SE
Laser Delivery Type	Articulated Arm with Handpiece			SE
Light Transfer Method	Handpiece revolver			SE

Table 2. General Comparison of Indication for use

	Proposed Device	Predicate Device #3	SE decision
K Number	K220794	K192539	-
Manufacturer	Tentech Co., Ltd.	El. EN. Electronic Engineering SPA	-
Trade Name	Photo therapy unit	Deka Luxea "LAZUR Pulsed Light handpiece"	-
Indications for Use	The Photo therapy unit (model: 10PL) is intended for use in surgical and aesthetic applications in dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV. Wavelength Condition 415-950 nm Melasma 570-950 nm Melasma, Rosacea 590-950 nm Rosacea, Port wine stains	<u>LAZUR Pulsed Light handpiece:</u> The handpiece (with and without contact-cooling) is indicated for: - The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).	
Wavelength	415-950 nm	420-950nm	SE

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8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Electrical Safety, Electromagnetic Compatibility Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Standard (Edition)	Standard Title
AASI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010/A1:2013	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
IEC 60601-2-57:2011	Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 62471:2006	Photobiological safety of lamps and lamp systems.

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2) Software Validation

The 10PL contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on November 4, 2021.

3) Biocompatibility

The part of 10PL in contact with the patient was verified and demonstrated for the safety of materials through the biocompatibility test in accordance with ISO 10993-1.

- Cytotoxicity test according to ISO 10993-5
- Intracutaneous (intradermal) reactivity test according to ISO 10993-10
- Skin sensitization test according to ISO 10993-10

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9. Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Tentech Co,. Ltd. concludes that the 10PL is substantially equivalent to predicate devices as described herein.