March 19, 2026

Wuhan PHOMED Technology Company , Ltd.
Huang Bill
General manager
Rm. 02, 3f, Bldg. 2, Gezhouba Sun City, # 40 Gaoxin
4th Rd., E. Lake New Technology Development Zone
Wuhan, Hubei 430200
China

Re: K253965
Trade/Device Name: CureLight Medical Diode Laser Systems (CureLight F2-A15; CureLight F2-B15; CureLight F2-A30; CureLight F2-B30; CureLight F3-AB30; CureLight F3-AB60.)
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: PDZ, ILY
Dated: December 11, 2025
Received: December 11, 2025

Dear Huang Bill:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.03.19 12:19:02 -04'00'

for Tanisha Hithe
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253965

Please provide the device trade name(s).

CureLight Medical Diode Laser Systems (CureLight F2-A15;
CureLight F2-B15;
CureLight F2-A30;
CureLight F2-B30;
CureLight F3-AB30;
CureLight F3-AB60.)

Please provide your Indications for Use below.

(1) The CureLight Medical Diode Laser Systems, include model: CureLight F2-A15 and CureLight F2-A30, are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.
(2) The CureLight Medical Diode Laser Systems, model: CureLight F2-B15, CureLight F2-B30, CureLight F3-AB30 and CureLight F3-AB60 are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.
The CureLight Medical Diode Laser Systems, model: CureLight F2-B15, CureLight F2-B30, CureLight F3-AB30 and CureLight F3-AB60 are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253965 510(k) Summary

I SUBMITTER

Wuhan PHOMED Technology Co., Ltd.

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Contact Person: Bill Huang

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Email: bill.huang@phomedlaser.com

Date Prepared: December 10, 2025

Ⅱ DEVICE

Name of Device:	CureLight Medical Diode Laser Systems
Model:	CureLight F2-A15, CureLight F2-B15, CureLight F2-A30, CureLight F2-B30, CureLight F3-AB30, CureLight F3-AB60
Regulation number:	21 CFR 890.5500 21 CFR 878.4810
Regulation name:	Infrared lamp Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name:	Lamp, Infrared, Therapeutic Heating Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis
Regulatory class:	Class Ⅱ
Product code:	ILY, PDZ

Ⅲ PREDICATE DEVICE

Primary Predicate Device

Trade name:	Medical diode laser systems
Classification name:	Lamp, Infrared, Therapeutic Heating

	Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis
Regulation number:	21 CFR 890.5500
	21 CFR 878.4810
Regulation name:	Infrared lamp
	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory class:	Class Ⅱ
Product code:	ILY, PDZ
Submitter:	Gigaalaser Company Ltd.
510(k) number:	K242755

Co-predicate Device	
Trade name:	Diowave Laser System
Classification name:	Lamp, Infrared, Therapeutic Heating
Regulation number:	21 CFR 890.5500
Regulation name:	Infrared lamp
Regulatory class:	Class Ⅱ
Product code:	ILY
Submitter:	TECHNOLOGICAL MEDICAL ADVANCMENTS, INC. (TMA)
510(k) number:	K121363

IV. DEVICE DESCRIPTION

The “CureLight Medical Diode Laser Systems”, include model: CureLight F2-A15, CureLight F2-A30, CureLight F2-B15, CureLight F2-B30, CureLight F3-AB30 and CureLight F3-AB60. Which consist of three main components:

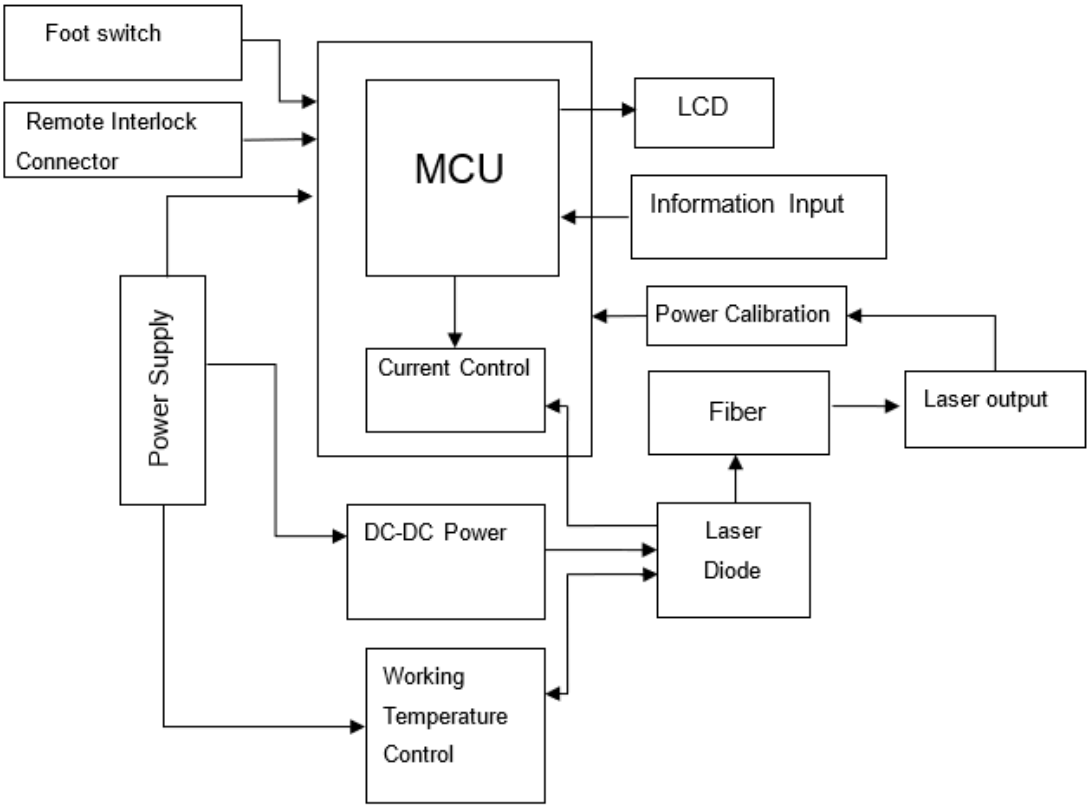
(1) Main device;

(2) Foot switch;

(3) Accessories.

Diode laser is a kind of laser with semiconductor as working material. It consists of working material, cavity resonator and power source.

The diode laser for this unit is GaAlAs diode bar, and the wavelength is 810/980nm. It features impact structure, high efficiency and long lifetime. Generally, the beam shall be emitted as the big beam divergence of the laser from the diode. With the PHOMED’S unique fiber-coupling technology, the laser beam can be coupled efficiently into the fiber.



MCU (Micro Controller Unit) is the control center of system. MCU controls the drive board and temperature system by changing operating current. The operating power supply is the power source of the whole system. It supplies power for MCU, diode laser module by DC-DC conversion module and temp system by temp-control circuit. MCU controls the drive current of diode laser module by adjusting the DC-DC module and current-control circuit. The MCU

has three external input sources: footswitch, remote interlock connector and information input from the touch units, it has one external output unit: display terminal. The diode laser module provides laser power output by fiber with optical fiber coupling system.

V. INDICATIONS FOR USE

(1) The CureLight Medical Diode Laser Systems, include model: CureLight F2-A15 and CureLight F2-A30, are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

(2) The CureLight Medical Diode Laser Systems, model: CureLight F2-B15, CureLight F2-B30, CureLight F3-AB30 and CureLight F3-AB60 are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

The CureLight Medical Diode Laser Systems, model: CureLight F2-B15, CureLight F2-B30, CureLight F3-AB30 and CureLight F3-AB60 are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1 Substantial equivalence discussion (CureLight Medical diode laser systems, Model: CureLight F2-A15)

Item	Proposed device	Primary predicate device	Discussion
510k Number	/	K242755	/
Proprietary Name	CureLight Medical diode laser systems	Medical diode laser systems	/
Model	CureLight F2-A15	GBOX-15AB	/
Product Code	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class Ⅱ	Class Ⅱ	Identical
Indication for Use	The CureLight Medical Diode Laser Systems, model: CureLight F2-A15 is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.	The Medical Diode Laser Systems, model: GBOX-15AB is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to	Identical

		temporarily increase local blood circulation.	
Laser type	diode laser	diode laser	Identical
Wavelength	810nm±20nm	810 ± 10nm; 980 ± 10nm;	Different Comment 1
Output Power	0-15W (±20%)	1W-15W(±10%)	SE
Energy Density(ED) / (Fluence)	≤1.55 J/cm^2 (Per second)	0.05~1.55 J/cm2 (Per second)	SE
Power Density	≤1.55 W/cm^2	0.05~1.55 W/cm2	SE
Spot Diameter	4~5 cm	3.5~5 cm	Different Comment 2
Working Distance	0 cm~2 cm for therapy handpiece 1 2 cm~3 cm for therapy handpiece 2	3~5 cm	Different Comment 3
Treatment Angle	Perpendicular to the treatment area	Perpendicular to the treatment area	Identical
Applied Part Moving Speed	3~5 cm/s	3~5 cm/s	Identical
Operation Mode	CW, repeat pulse	CW, single pulse, repeat pulse	Different Comment 4
Pulse Width	50μs-1s	25μs-10s	Different Comment 5
Pulse Repetition	1Hz-10KHz	1Hz-20KHz	Different

Rate			Comment 6
Treatment Methods	Contact, Non-contact.	Non-contact.	Different Comment 7
Applied Part	Handpiece	Handpiece	Identical
Transmission System	400μm fibers with metal protective armors.	fibers of 600μm with SMA905 connector.	Different Comment 8
Aiming Beam	Diode laser of 635nm(±20nm), power ＜5mW, adjustable brightness.	Diode laser of 650nm, power ＜ 5mW, adjustable brightness.	SE
Operation Interface	Color LCD touch screen	Color LCD touch screen	Identical
Power Supply	~ 110-230V, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 350VA	SE
Laser Class	4	4	Identical
Safety Classification	Class Ⅰ Type B	Class Ⅰ Type B	Identical
Cooling	Air	Air	Identical
Waterproof Level	IPX1	IPX1	Identical
Footswitch Waterproof Level	IPX8	IPX8	Identical

Discussion:

Clinical:

Indication for Use claimed by proposed device is the same with the predicate device K242755 (GBOX-15AB).

Technology:

The subject device has the same output power of diode laser to achieve its intended use.

The energy density (ED) / (fluence), power density, treatment angle, applied part, moving speed, treatment methods and etc. are either identical to the predicate. The main differences are wavelength, spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods and transmission system.

Comment 1 Wavelength:

The wavelength of the proposed device: 810nm±20nm, which is different to the predicate device, K242755 (GBOX-15AB): 810 ± 10nm; 980 ± 10nm, but the wavelength of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 2 Spot Diameter:

The spot diameter of the proposed device: 4~5 cm, which is different to the predicate device, K242755 (GBOX-15AB): 3.5~5 cm, but the spot diameter of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 3 Working Distance:

The working distance of the proposed device: 0 cm~2 cm for therapy handpiece 1; 2 cm~3 cm for therapy handpiece 2, which is different to the predicate device, K242755: 3~5 cm.

The working distance of proposed device is shorter because the therapy handpiece head has a length of 3cm. Therefore, the actual distance from the laser light source at the end of the laser output port to the treatment end is 3 cm~5 cm for therapy handpiece 1

which is identical with the predicate device, K242755 (GBOX-15AB):3~5 cm; 5 cm~6 cm for therapy handpiece 2, a little longer:1cm than the working distance of predicate device, K242755 (GBOX-15AB): 3~5 cm, but the energy density(ED) / (fluence) and power density are all within the scope of what predicate device claims and it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 4 Operation mode:

The operation mode of the proposed device: CW, repeat pulse is different to the predicate device, K242755 (GBOX-15AB): CW, single pulse, repeat pulse. but the operation mode of the proposed device is within the scope of what predicate device, K242755 (GBOX-15AB) claims. This difference does not affect the safety and effectiveness of the device.

Comment 5 Pulse width:

The pulse width of the proposed device: 50μs-1s, which is different to the predicate device, K242755 (GBOX-15AB): 25μs-10s, but the pulse width of the proposed device is within the scope of what predicate device, K242755 (GBOX-15AB) claims. This difference does not affect the safety and effectiveness of the device.

Comment 6 Pulse repetition rate:

The pulse repetition rate of the subject device: 1Hz-10KHz, which is different to the predicate device, K242755 (GBOX-15AB): 1Hz-20KHz, but the pulse repetition rate of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 7 Treatment Methods:

The treatment methods of the subject device (Contact, Non-contact), which is different to the predicate device (Non-contact), but it meets the clinical needs. Contact mode is convenient for doctors to operate, which is more labor-saving. Moreover, the therapy handpiece head of therapy handpiece 1 has been evaluated and tested for biocompatibility as required, and the test results meet the requirements. This difference does not affect the safety and effectiveness of the device.

Comment 8 Transmission system

The transmission system of the subject device (400μm fibers with metal protective armors), which is different to the predicate device (fibers of 600μm with SMA905 connector).

The transmission system only transmits laser energy. Although the optical fiber core diameter of optical fiber transmission system is different, but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Conclusion:

The indication for use of the subject device claimed by proposed device is the same with the predicate device.

The proposed device uses same diode lasers technology as that used by the predicates. The core output parameters of the proposed device are identical to the predicates. The differences only exist in such contents: spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods and transmission system, that all can be controlled in range of application. These differences do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

So, the proposed devices are Substantially Equivalent (SE) to existing legally marketed predicate devices.

Table 2 Substantial equivalence discussion (CureLight Medical diode laser systems, Model: CureLight F2-A30)

Item	Proposed device	Primary predicate device	Co-predicate device	Discussion
510k Number	/	K242755	K121363	/
Proprietary Name	CureLight Medical diode laser systems	Medical diode laser systems	Diowave Laser System	/
Model	CureLight F2-A30	VELAS Ⅱ-30A	Diowave 30W	/
Product Code	ILY	ILY	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Identical
Classification	Class Ⅱ	Class Ⅱ	Class Ⅱ	Identical
Indication for Use	The CureLight Medical Diode Laser Systems, model: CureLight F2-A30 is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase	The Medical Diode Laser Systems, model: VELAS Ⅱ-30A is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase	The Diowave Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating, tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue,	Identical

	local blood circulation.	local blood circulation.	and to temporarily increase local blood circulation.	
Laser type	diode laser	diode laser	diode laser	Identical
Wavelength	810nm±20nm	810 ± 10nm	810nm±10nm, 980nm±10nm	SE
Output Power	0-30W (±20%)	1W-30W(±20%)	N/A	SE
Energy Density(ED) / (Fluence)	≤3.1 J/cm^2 (Per second)	0.05~3.1 J/cm^2 (Per second)	N/A	SE
Power Density	≤3.1 W/cm^2	0.05~3.1 W/cm^2	N/A	SE
Spot Diameter	4~5 cm	3.5~5 cm	N/A	Different Comment 1
Working Distance	0 cm~2 cm for therapy handpiece 1 2 cm~3 cm for therapy handpiece 2	3~5 cm	N/A	Different Comment 2
Treatment Angle	Perpendicular to the treatment area	Perpendicular to the treatment area	N/A	Identical
Applied Part Moving Speed	3~5 cm/s	3~5 cm/s	N/A	Identical
Operation Mode	CW, repeat pulse	CW, single pulse, repeat pulse	N/A	Different Comment 3
Pulse Width	50μs-1s	10ms-1s	N/A	Different Comment 4

Pulse Repetition Rate	1Hz-10KHz	1Hz-50Hz	N/A	Different Comment 5
Treatment Methods	Contact, Non-contact.	Non-contact.	Non-contact	Different Comment 6
Applied Part	Handpiece	Handpiece	Handpiece	Identical
Transmission System	400μm fibers with metal protective armors.	fibers of 600μm with SMA905 connector.	fibers of 400μm, 600μm and 1000μm with SMA905 connector	Different Comment 7
Aiming Beam	Diode laser of 635nm(±20nm), power ＜ 5mW, adjustable brightness.	Diode laser of 650nm, power≤2mW, adjustable brightness.	Diode laser of 650nm power max. ＜ 5mW, adjustable brightness.	SE
Operation Interface	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen	Identical
Power Supply	~ 110-230V, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	SE
Laser Class	4	4	4	Identical
Safety Classification	Class Ⅰ Type B	Class Ⅰ Type B	Class Ⅰ Type B	Identical
Cooling	Air	Air	Air	Identical
Waterproof Level	IPX1	IPX1	IPX1	Identical

Footswitch Waterproof Level	IPX8	IPX8	IPX8	Identical

Discussion:

Clinical:

Indication for use claimed by proposed device is the same with the predicate device K242755 (VELAS Ⅱ-30A) and K121363.

Technology:

The subject device has the same wavelengths and output power of diode laser to achieve its intended use.

The energy density (ED) / (fluence), power density, treatment angle, applied part, moving speed, treatment methods and etc. are either identical to the predicate. The main differences are spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods and transmission system.

Comment 1 Spot Diameter:

The spot diameter of the proposed device: 4~5 cm, which is different to the predicate device, K242755 (VELAS Ⅱ-30A): 3.5~5 cm, but the spot diameter of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 2 Working Distance:

The working distance of the proposed device: 0 cm~2 cm for therapy handpiece 1; 2 cm~3 cm for therapy handpiece 2, which is different to the predicate device, K242755 (VELAS Ⅱ-30A): 3~5 cm.

The working distance of proposed device is shorter because the therapy handpiece head has a length of 3cm. Therefore, the actual distance from the laser light source at the end of the laser output port to the treatment end is 3 cm~5 cm for therapy handpiece 1

which is identical with the predicate device, K242755 (VELAS Ⅱ-30A): 3~5 cm; 5 cm~6 cm for therapy handpiece 2, a little longer:1cm than the working distance of predicate device, K242755 (VELAS Ⅱ-30A): 3~5 cm, but the energy density(ED) / (fluence) and power density are all within the scope of what predicate device, K242755 (VELAS Ⅱ-30A) claims and it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Comment 3 Operation mode:

The operation mode of the proposed device: CW, repeat pulse is different to the predicate device, K242755 (VELAS Ⅱ-30A): CW, single pulse, repeat pulse. but the operation mode of the proposed device is within the scope of what predicate device, K242755 (VELAS Ⅱ-30A) claims. This difference does not affect the safety and effectiveness of the device.

Comment 4 Pulse width:

The pulse width of the proposed device: 50μs-1s, which is different to the predicate device, K242755 (VELAS Ⅱ-30A): 10ms-1s.

The difference in pulse width range (specifically the extension to 50 μs) is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30A). The expanded parameter range operates within the same thermal safety margins and is justified by the overlapping therapeutic effect of elevating tissue temperature.

Comment 5 Pulse repetition rate:

The pulse repetition rate of the subject device: 1Hz-10KHz, which is different to the predicate device, K242755 (VELAS Ⅱ-30A): 1Hz-50Hz.

The difference in pulse repetition rate: 1Hz-10KHz and 1Hz-50Hz is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30A).

Comment 6 Treatment Methods:

The treatment methods of the subject device (Contact, Non-contact), which is different to the predicate device (Non-contact), but it meets the clinical needs. Contact mode is convenient for doctors to operate, which is more labor-saving. Moreover, the therapy handpiece head of therapy handpiece 1 has been evaluated and tested for biocompatibility as required, and the test results meet the requirements. This difference does not affect the safety and effectiveness of the device.

Comment 7 Transmission system

The transmission system of the subject device (400μm fibers with metal protective armors), which is different to the predicate device (fibers of 600μm with SMA905 connector).

The transmission system only transmits laser energy. Although the optical fiber core diameter of optical fiber transmission system is different, but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Conclusion:

The indication for use of the subject device claimed by proposed device is the same with the predicate device.

The proposed device uses same diode lasers technology as that used by the predicates. The core output parameters of the proposed device are identical to the predicates. The differences only exist in such contents: spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods and transmission system, that all can be controlled in range of application. These differences do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

So, the proposed devices are Substantially Equivalent (SE) to existing legally marketed predicate devices.

Table 3 Substantial equivalence discussion (CureLight Medical diode laser systems, Model: CureLight F2-B15)

Item	Proposed device	Primary predicate device	Co-predicate device	Discussion
510k Number	/	K242755	K121363	/
Proprietary Name	CureLight Medical diode laser systems	Medical diode laser systems	Diowave Laser System	/
Model	CureLight F2-B15	VELAS Ⅱ-30B	Diowave 30W	/
Product Code	ILY, PDZ	ILY, PDZ	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500, 21 CFR 878.4810	21 CFR 890.5500	Identical
Classification	Class Ⅱ	Class Ⅱ	Class Ⅱ	Identical
Indication for Use	The CureLight Medical Diode Laser Systems, model: CureLight F2-B15 are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase	The Medical Diode Laser Systems, model: VELAS Ⅱ-30B is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase	The Diowave Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating, tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue,	SE

	local blood circulation. The CureLight Medical Diode Laser Systems, model: CureLight F2-B15 are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	local blood circulation. The Medical Diode Laser Systems, model: VELAS Ⅱ -30B is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	and to temporarily increase local blood circulation.	
Laser type	diode laser	diode laser	diode laser	Identical
Wavelength	980nm±20nm	980 ± 10nm	810nm±10nm, 980nm±10nm	SE
Output Power	Physical therapy mode: 0-15W (±20%) General mode: 0-10W (±20%)	Physical therapy mode: 1W-30W (±20%) General mode: 1W-10W (±20%), 980nm only	N/A	Different Comment 1
Energy Density(ED) / (Fluence)	Physical therapy mode: ≤1.55 J/cm^2 (Per second) General mode: ≤39.8 J/cm^2 (Per second)	Physical therapy mode: 0.05~3.1 J/cm^2 (Per second) General mode: 1.7~39.8 J/cm^2 (Per second)	N/A	Different Comment 2
Power Density	Physical therapy mode: ≤1.55 W/cm^2 General mode: ≤39.8 W/cm^2	Physical therapy mode: 0.05~3.1 W/cm^2 General mode: 1.7~39.8 W/cm^2	N/A	Different Comment 3

Spot Diameter	Physical therapy mode: 4~5 cm General mode: 5~6 mm	Physical therapy mode: 3.5~5 cm General mode: 4~5 mm	N/A	Different Comment 4
Working Distance	Physical therapy mode: 0 cm~2 cm for therapy handpiece 1 2 cm~3 cm for therapy handpiece 2 General mode: 3~4 mm	Physical therapy mode: 3~5 cm General mode: 3~4 mm	N/A	Different Comment 5
Treatment Angle	Perpendicular to the treatment area	Perpendicular to the treatment area	N/A	Identical
Applied Part Moving Speed	Physical therapy mode: 3~5 cm/s General mode: 1~2 cm/s	Physical therapy mode: 3~5 cm/s General mode: 1~2 cm/s	N/A	Identical
Operation Mode	Physical therapy mode: CW, repeat pulse General mode: repeat pulse	Physical therapy mode: CW, single pulse, repeat pulse repeat pulse: repeat pulse	N/A	Different Comment 6
Pulse Width	Physical therapy mode: 50μs-1s General mode: Ton: 10ms Toff: 10ms, 20ms	Physical therapy mode: 10ms-1s General mode: Ton: 10ms Toff: 10ms, 20ms	N/A	Different Comment 7
Pulse Repetition Rate	Physical therapy mode: 1Hz-10KHz General mode: 33.3Hz/50Hz	General mode: 1Hz-50Hz General mode: 33.3Hz/50Hz	N/A	Different Comment 8
Treatment Methods	Physical therapy mode: Contact, Non-contact.	Non-contact.	Non-contact	Different Comment 9

	General mode: Non-contact			
Treatment Mode	Physical therapy mode, general mode	Physical therapy mode, general mode	/	Identical
Applied Part	Handpiece	Physical therapy mode: Handpiece General mode: Fiber	Handpiece	Different Comment 10
Transmission System	400μm fibers with metal protective armors.	fibers of 600μm with SMA905 connector.	fibers of 400μm, 600μm and 1000μm with SMA905 connector	Different Comment 11
Aiming Beam	Diode laser of 635nm(±20nm), power ＜ 5mW, adjustable brightness.	Diode laser of 650nm, power≤2mW, adjustable brightness.	Diode laser of 650nm power max. ＜ 5mW, adjustable brightness.	SE
Operation Interface	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen	Identical
Power Supply	~ 110-230V, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	SE
Laser Class	4	4	4	Identical
Safety Classification	Class Ⅰ Type B	Class Ⅰ Type B	Class Ⅰ Type B	Identical
Cooling	Air	Air	Air	Identical
Waterproof Level	IPX1	IPX1	IPX1	Identical

Footswitch Waterproof Level	IPX8	IPX8	IPX8	Identical

Discussion:

Clinical:

Indication for use claimed by proposed device is the same with the predicate device K242755 (VELAS Ⅱ-30B).

Technology:

The subject device has the same wavelength of diode laser to achieve its intended use.

The treatment angle, moving speed, treatment methods and etc. are either identical to the predicate. The main differences are output power, energy density (ED) / (fluence), power density, spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods, applied part and transmission system.

Comment 1 Output Power:

Physical therapy mode:

The output power of the proposed device: 0-15W (±20%), which is different to the predicate device, K242755 (VELAS Ⅱ-30B): 1W-30W (±20%), but the output power of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The output power of the proposed device: 0-10W (±20%) is substantial equivalence with the predicate device, K242755 (VELAS Ⅱ-30B): 1W-10W (±20%) claims.

Comment 2 Energy Density (ED) / (Fluence):

Physical therapy mode:

The energy density (ED) / (fluence) of the proposed device: ≤1.55 J/cm^2 (Per second), which is different to the predicate device, K242755 (VELAS Ⅱ-30B): 0.05~3.1 J/cm^2 (Per second), but the Energy Density (ED) / (Fluence) of the proposed device is within the scope of predicate device, K242755 (VELAS Ⅱ-30B) claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The energy density (ED) / (fluence) of the proposed device: ≤39.8 J/cm^2 (Per second) is substantial equivalence with the predicate device, K242755 (VELAS Ⅱ-30B): 1.7~39.8 J/cm^2 (Per second) claims.

Comment 3 Power Density:

Physical therapy mode:

The power density of the proposed device: ≤1.55 W/cm^2, which is different to the predicate device, K242755 (VELAS Ⅱ-30B): 0.05~3.1 W/cm^2, but the power density of the proposed device is within the scope of predicate device, K242755 (VELAS Ⅱ-30B) claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The power density of the proposed device: ≤39.8 W/cm^2 is substantial equivalence with the predicate device, K242755 (VELAS Ⅱ-30B): 1.7~39.8 W/cm^2 claims.

Comment 4 Spot Diameter:

Physical therapy mode:

The spot diameter of the proposed device: 4~5 cm, which is different to the predicate device, K242755: 3.5~5 cm, but the spot diameter of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The spot diameter of the proposed device: 5~6 mm, which is different to the predicate device, K242755: 4~5 mm, but the energy density (ED) / (fluence) and power density of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 5 Working Distance:

Physical therapy mode:

The working distance of the proposed device: 0 cm~2 cm for therapy handpiece 1; 2 cm~3 cm for therapy handpiece 2, which is different to the predicate device, K242755: 3~5 cm.

The working distance of proposed device is shorter because the therapy handpiece head has a length of 3cm. Therefore, the actual distance from the laser light source at the end of the laser output port to the treatment end is 3 cm~5 cm for therapy handpiece 1 which is identical with the predicate device: 3~5 cm; 5 cm~6 cm for therapy handpiece 2, a little longer:1cm than the working distance of predicate device: 3~5 cm, but the energy density(ED) / (fluence) and power density are all within the scope of what predicate device claims and it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

General mode:

The working distance of the proposed device is the same with the predicate device.

Comment 6 Operation mode:

Physical therapy mode:

The operation mode of the proposed device (CW, repeat pulse) is different to the predicate device (CW, single pulse, repeat pulse). but the operation mode of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The operation mode of the proposed device is the same with the predicate device.

Comment 7 Pulse width:

Physical therapy mode:

The pulse width of the proposed device: 50μs-1s, which is different to the predicate device, K242755 (VELAS Ⅱ-30B): 10ms-1s.

The difference in pulse width range (specifically the extension to 50 μs) is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30B). The expanded parameter range operates within the same thermal safety margins and is justified by the overlapping therapeutic effect of elevating tissue temperature.

General mode:

The pulse width of the proposed device is the same with the predicate device.

Comment 8 Pulse repetition rate:

Physical therapy mode:

The pulse repetition rate of the subject device: 1Hz-10KHz, which is different to the predicate device, K242755 (VELAS Ⅱ-30B): 1Hz-50Hz.

The difference in pulse repetition rate: 1Hz-10KHz and 1Hz-50Hz is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30B).

General mode:

The pulse repetition rate of the proposed device is the same with the predicate device.

Comment 9 Treatment Methods:

Physical therapy mode:

The treatment methods of the subject device (Contact, Non-contact), which is different to the predicate device (Non-contact), but it meets the clinical needs. Contact mode is convenient for doctors to operate, which is more labor-saving. Moreover, the therapy handpiece head of therapy handpiece 1 has been evaluated and tested for biocompatibility as required, and the test results meet the requirements. This difference does not affect the safety and effectiveness of the device.

General mode:

The treatment methods of the proposed device are the same with the predicate device.

Comment 10 Applied Part:

Physical therapy mode:

The applied part of the proposed device are the same with the predicate device.

General mode:

The applied part of the subject device (Handpiece), which is different to the predicate device (Fiber), but it meets the clinical needs. The applied part: Handpiece and fiber have the same function of transmitting laser energy to the treatment area, but handpiece is convenient for doctors to operate. This difference does not affect the safety and effectiveness of the device.

Comment 11 Transmission system

The transmission system of the subject device (400μm fibers with metal protective armors), which is different to the predicate device (fibers of 600μm with SMA905 connector).

The transmission system only transmits laser energy. Although the optical fiber core diameter of optical fiber transmission system is different, but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Conclusion:

The indication for use of the subject device claimed by proposed device is the same with the predicate device.

The proposed device uses same diode lasers technology as that used by the predicates. The core output parameters of the proposed device are identical to the predicates. The differences only exist in such contents: output power, energy density (ED) / (fluence), power density, spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods, applied part and transmission system, that all can be controlled in range of application. These differences do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

So, the proposed devices are Substantially Equivalent (SE) to existing legally marketed predicate devices.

Table 4 Substantial equivalence discussion (CureLight Medical diode laser systems, Model: CureLight F2-B30, CureLight F3-AB30)

Item	Proposed device	Primary predicate device	Co-predicate device	Discussion
510k Number	/	K242755	K121363	/
Proprietary Name	CureLight Medical diode laser systems	Medical diode laser systems	Diowave Laser System	/
Model	CureLight F2-B30, CureLight F3-AB30	VELAS Ⅱ-30A, VELAS Ⅱ-30B	Diowave 30W	/
Product Code	ILY, PDZ	ILY, PDZ	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500, 21 CFR 878.4810	21 CFR 890.5500	Identical
Classification	Class Ⅱ	Class Ⅱ	Class Ⅱ	Identical
Indication for Use	The CureLight Medical Diode Laser Systems, model: CureLight F2-B30 and CureLight F3-AB30 are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis,	The Medical Diode Laser Systems, model: VELAS Ⅱ-30A and VELAS Ⅱ-30B is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of	The Diowave Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating, tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting	SE

	promoting relaxation of muscle tissue, and to temporarily increase local blood circulation. The CureLight Medical Diode Laser Systems, model: CureLight F2-B30 and CureLight F3-AB30 are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	muscle tissue, and to temporarily increase local blood circulation. The Medical Diode Laser Systems, model: VELAS Ⅱ -30B is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	relaxation of muscle tissue, and to temporarily increase local blood circulation.	
Laser type	diode laser	diode laser	diode laser	Identical
Wavelength	CureLight F2-B30: 980nm±20nm CureLight F3-AB30: 810nm±20nm, 980nm±20nm	VELAS Ⅱ-30A: 810 ± 10nm VELAS Ⅱ-30B: 980 ± 10nm	810nm±10nm, 980nm±10nm	SE
Output Power	Physical therapy mode: 0-30W (±20%) General mode: 0-10W (±20%), 980nm only	Physical therapy mode: 1W-30W (±20%) General mode: 1W-10W (±20%), 980nm only	N/A	SE
Energy Density(ED) / (Fluence)	Physical therapy mode: ≤3.1 J/cm^2 (Per second) General mode: ≤39.8 J/cm^2 (Per	Physical therapy mode: 0.05~3.1 J/cm^2 (Per second) General mode: 1.7~39.8 J/cm^2 (Per	N/A	SE

	second)	second)		
Power Density	Physical therapy mode: ≤3.1 W/cm^2 General mode: ≤39.8 W/cm^2	Physical therapy mode: 0.05~3.1 W/cm^2 General mode: 1.7~39.8 W/cm^2	N/A	SE
Spot Diameter	Physical therapy mode: 4~5 cm General mode: 5~6 mm	Physical therapy mode: 3.5~5 cm General mode: 4~5 mm	N/A	Different Comment 1
Working Distance	Physical therapy mode: 0 cm~2 cm for therapy handpiece 1 2 cm~3 cm for therapy handpiece 2 General mode: 3~4 mm	Physical therapy mode: 3~5 cm General mode: 3~4 mm	N/A	Different Comment 2
Treatment Angle	Perpendicular to the treatment area	Perpendicular to the treatment area	N/A	Identical
Applied Part Moving Speed	Physical therapy mode: 3~5 cm/s General mode: 1~2 cm/s	Physical therapy mode: 3~5 cm/s General mode: 1~2 cm/s	N/A	Identical
Operation Mode	Physical therapy mode: CW, repeat pulse General mode: repeat pulse	Physical therapy mode: CW, single pulse, repeat pulse repeat pulse: repeat pulse	N/A	Different Comment 3
Pulse Width	Physical therapy mode: 50μs-1s General mode: Ton: 10ms Toff: 10ms, 20ms	Physical therapy mode: 10ms-1s General mode: Ton: 10ms Toff: 10ms, 20ms	N/A	Different Comment 4
Pulse	Physical therapy mode: 1Hz-10KHz	General mode: 1Hz-50Hz	N/A	Different

Repetition Rate	General mode: 33.3Hz/50Hz	General mode: 33.3Hz/50Hz		Comment 5
Treatment Methods	Physical therapy mode: Contact, Non-contact. General mode: Non-contact	Non-contact.	Non-contact	Different Comment 6
Treatment Mode	Physical therapy mode, general mode	Physical therapy mode, general mode	/	Identical
Applied Part	Handpiece	Physical therapy mode: Handpiece General mode: Fiber	Handpiece	Different Comment 7
Transmission System	400μm fibers with metal protective armors.	fibers of 600μm with SMA905 connector.	fibers of 400μm, 600μm and 1000μm with SMA905 connector	Different Comment 8
Aiming Beam	Diode laser of 635nm(±20nm), power ＜ 5mW, adjustable brightness.	Diode laser of 650nm, power≤2mW, adjustable brightness.	Diode laser of 650nm power max. ＜ 5mW, adjustable brightness.	SE
Operation Interface	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen	Identical
Power Supply	~ 110-230V, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	SE
Laser Class	4	4	4	Identical
Safety Classification	Class Ⅰ Type B	Class Ⅰ Type B	Class Ⅰ Type B	Identical

Cooling	Air	Air	Air	Identical
Waterproof Level	IPX1	IPX1	IPX1	Identical
Footswitch Waterproof Level	IPX8	IPX8	IPX8	Identical

Discussion:

Clinical:

Indication for use claimed by proposed device is the same with the predicate device K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B).

Technology:

The subject device has the same wavelengths and output power of diode laser to achieve its intended use.

The energy density (ED) / (fluence), power density, treatment angle, moving speed, treatment methods and etc. are either identical to the predicate. The main differences are spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods, applied part and transmission system.

Comment 1 Spot Diameter:

Physical therapy mode:

The spot diameter of the proposed device: 4~5 cm, which is different to the predicate device, K242755: 3.5~5 cm, but the spot diameter of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The spot diameter of the proposed device: 5~6 mm, which is different to the predicate device, K242755: 4~5 mm, but the energy density (ED) / (fluence) and power density of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 2 Working Distance:

Physical therapy mode:

The working distance of the proposed device: 0 cm~2 cm for therapy handpiece 1; 2 cm~3 cm for therapy handpiece 2, which is different to the predicate device, K242755: 3~5 cm.

The working distance of proposed device is shorter because the therapy handpiece head has a length of 3cm. Therefore, the actual distance from the laser light source at the end of the laser output port to the treatment end is 3 cm~5 cm for therapy handpiece 1 which is identical with the predicate device: 3~5 cm; 5 cm~6 cm for therapy handpiece 2, a little longer:1cm than the working distance of predicate device: 3~5 cm, but the energy density(ED) / (fluence) and power density are all within the scope of what predicate device claims and it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

General mode:

The working distance of the proposed device is the same with the predicate device.

Comment 3 Operation mode:

Physical therapy mode:

The operation mode of the proposed device (CW, repeat pulse) is different to the predicate device (CW, single pulse, repeat pulse). but the operation mode of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The operation mode of the proposed device is the same with the predicate device.

Comment 4 Pulse width:

Physical therapy mode:

The pulse width of the proposed device: 50μs-1s, which is different to the predicate device, K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B): 10ms-1s.

The difference in pulse width range (specifically the extension to 50 μs) is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B). The expanded parameter range operates within the same thermal safety margins and is justified by the overlapping therapeutic effect of elevating tissue temperature.

General mode:

The pulse width of the proposed device is the same with the predicate device.

Comment 5 Pulse repetition rate:

Physical therapy mode:

The pulse repetition rate of the subject device: 1Hz-10KHz, which is different to the predicate device, K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B): 1Hz-50Hz.

The difference in pulse repetition rate: 1Hz-10KHz and 1Hz-50Hz is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B).

General mode:

The pulse repetition rate of the proposed device is the same with the predicate device.

Comment 6 Treatment Methods:

Physical therapy mode:

The treatment methods of the subject device (Contact, Non-contact), which is different to the predicate device (Non-contact), but it meets the clinical needs. Contact mode is convenient for doctors to operate, which is more labor-saving. Moreover, the therapy handpiece head of therapy handpiece 1 has been evaluated and tested for biocompatibility as required, and the test results meet the requirements. This difference does not affect the safety and effectiveness of the device.

General mode:

The treatment methods of the proposed device are the same with the predicate device.

Comment 7 Applied Part:

Physical therapy mode:

The applied part of the proposed device are the same with the predicate device.

General mode:

The applied part of the subject device (Handpiece), which is different to the predicate device (Fiber), but it meets the clinical needs. The applied part: Handpiece and fiber have the same function of transmitting laser energy to the treatment area, but handpiece is convenient for doctors to operate. This difference does not affect the safety and effectiveness of the device.

Comment 8 Transmission system

The transmission system of the subject device (400μm fibers with metal protective armors), which is different to the predicate device (fibers of 600μm with SMA905 connector).

The transmission system only transmits laser energy. Although the optical fiber core diameter of optical fiber transmission system is different, but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Conclusion:

The indication for use of the subject device claimed by proposed device is the same with the predicate device.

The proposed device uses same diode lasers technology as that used by the predicates. The core output parameters of the proposed device are identical to the predicates. The differences only exist in such contents: spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods, applied part and transmission system, that all can be controlled in range of application. These differences do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

So, the proposed devices are Substantially Equivalent (SE) to existing legally marketed predicate devices.

Table 5 Substantial equivalence discussion (CureLight Medical diode laser systems, Model: CureLight F3-AB60)

Item	Proposed device	Primary predicate device	Co-predicate device	Discussion
510k Number	/	K242755	K121363	/
Proprietary Name	CureLight Medical diode laser systems	Medical diode laser systems	Diowave Laser System	/
Model	CureLight CureLight F3-AB60	VELAS Ⅱ-30A, VELAS Ⅱ-30B	Diowave 60W	/
Product Code	ILY, PDZ	ILY, PDZ	ILY	Identical
Regulation Number	21 CFR 890.5500	21 CFR 890.5500, 21 CFR 878.4810	21 CFR 890.5500	Identical
Classification	Class Ⅱ	Class Ⅱ	Class Ⅱ	Identical
Indication for Use	The CureLight Medical Diode Laser Systems, model: CureLight F3-AB60 are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily	The Medical Diode Laser Systems, model: VELAS Ⅱ-30A and VELAS Ⅱ-30B is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily	The Diowave Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating, tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue,	SE

	increase local blood circulation. The CureLight Medical Diode Laser Systems, model: CureLight F2-B30 and CureLight F3-AB30 are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	increase local blood circulation. The Medical Diode Laser Systems, model: VELAS Ⅱ -30B is also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	and to temporarily increase local blood circulation.	
Laser type	diode laser	diode laser	diode laser	Identical
Wavelength	810nm±20nm, 980nm±20nm	VELAS Ⅱ-30A: 810 ± 10nm VELAS Ⅱ-30B: 980 ± 10nm	810nm±10nm, 980nm±10nm	SE
Output Power	Physical therapy mode: 0-60W (±20%) General mode: 0-10W (±20%), 980nm only	Physical therapy mode: 1W-30W (±20%) General mode: 1W-10W (±20%), 980nm only	N/A	Different Comment 1
Energy Density(ED) / (Fluence)	Physical therapy mode: ≤6.2 J/cm^2 (Per second) General mode: ≤39.8 J/cm^2 (Per second)	Physical therapy mode: 0.05~3.1 J/cm^2 (Per second) General mode: 1.7~39.8 J/cm^2 (Per second)	N/A	Different Comment 2
Power Density	Physical therapy mode: ≤6.2 W/cm^2 General mode: ≤39.8 W/cm^2	Physical therapy mode: 0.05~3.1 W/cm^2	N/A	Different Comment 3

		General mode: 1.7~39.8 W/cm^2		
Spot Diameter	Physical therapy mode: 4~5 cm General mode: 5~6 mm	Physical therapy mode: 3.5~5 cm General mode: 4~5 mm	N/A	Different Comment 4
Working Distance	Physical therapy mode: 0 cm~2 cm for therapy handpiece 1 2 cm~3 cm for therapy handpiece 2 General mode: 3~4 mm	Physical therapy mode: 3~5 cm General mode: 3~4 mm	N/A	Different Comment 5
Treatment Angle	Perpendicular to the treatment area	Perpendicular to the treatment area	N/A	Identical
Applied Part Moving Speed	Physical therapy mode: 3~5 cm/s General mode: 1~2 cm/s	Physical therapy mode: 3~5 cm/s General mode: 1~2 cm/s	N/A	Identical
Operation Mode	Physical therapy mode: CW, repeat pulse General mode: repeat pulse	Physical therapy mode: CW, single pulse, repeat pulse repeat pulse: repeat pulse	N/A	Different Comment 6
Pulse Width	Physical therapy mode: 50μs-1s General mode: Ton: 10ms Toff: 10ms, 20ms	Physical therapy mode: 10ms-1s General mode: Ton: 10ms Toff: 10ms, 20ms	N/A	Different Comment 7
Pulse Repetition Rate	Physical therapy mode: 1Hz-10KHz General mode: 33.3Hz/50Hz	General mode: 1Hz-50Hz General mode: 33.3Hz/50Hz	N/A	Different Comment 8
Treatment	Physical therapy mode: Contact,	Non-contact.	Non-contact	Different

Methods	Non-contact. General mode: Non-contact			Comment 9
Treatment Mode	Physical therapy mode, general mode	Physical therapy mode, general mode	/	Identical
Applied Part	Handpiece	Physical therapy mode: Handpiece General mode: Fiber	Handpiece	Different Comment 10
Transmission System	400μm fibers with metal protective armors.	fibers of 600μm with SMA905 connector.	fibers of 400μm, 600μm and 1000μm with SMA905 connector	Different Comment 11
Aiming Beam	Diode laser of 635nm(±20nm), power ＜ 5mW, adjustable brightness.	Diode laser of 650nm, power≤2mW, adjustable brightness.	Diode laser of 650nm power max. ＜ 5mW, adjustable brightness.	SE
Operation Interface	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen	Identical
Power Supply	~ 110-230V, 50-60Hz, 200VA	100-240VAC, 50-60Hz, 350VA	100-240VAC, 50/60Hz, 350VA	SE
Laser Class	4	4	4	Identical
Safety Classification	Class Ⅰ Type B	Class Ⅰ Type B	Class Ⅰ Type B	Identical
Cooling	Air	Air	Air	Identical
Waterproof	IPX1	IPX1	IPX1	Identical

Level				
Footswitch Waterproof Level	IPX8	IPX8	IPX8	Identical

Discussion:

Clinical:

Indication for use claimed by proposed device is the same with the predicate device K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B).

Technology:

The subject device has the same wavelength of diode laser to achieve its intended use.

The treatment angle, moving speed, treatment methods and etc. are either identical to the predicate. The main differences are output power, energy density (ED) / (fluence), power density, spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods, applied part and transmission system.

Comment 1 Output Power:

Physical therapy mode:

The output power of the proposed device: 0-60W (±20%), which is different to the predicate device, K242755 (VELAS Ⅱ-30A and VELAS Ⅱ-30B): 1W-30W (±20%), but the output power of the proposed device is within the scope of predicate device, K121363 (Diowave 60W): Max. 60W claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The output power of the proposed device: 0-10W (±20%) is substantial equivalence with the predicate device, K242755 (VELAS Ⅱ-30B): 1W-10W (±20%) claims.

Comment 2 Energy Density (ED) / (Fluence):

Physical therapy mode:

The energy density (ED) / (fluence) of the proposed device: ≤6.2 J/cm^2 (Per second), which is different to the predicate device, K242755 (VELAS Ⅱ-30A and VELAS Ⅱ-30B): 0.05~3.1 J/cm^2 (Per second), but the Energy Density (ED) / (Fluence) of the proposed device will within the scope of predicate device, K121363 (Diowave 60W). This difference does not affect the safety and effectiveness of the device.

Energy Density (ED) / (Fluence):

ED = P*Time/S*Duty J/cm^2

All other conditions being equal, the higher the output power, the higher the energy density. At a maximum output power of 60W, the energy density will be twice as high as at a maximum output power of 30W. While the Max. ED≤3.1 J/cm^2 (Per second) at 30W, the Max. ED will ≤6.2 J/cm^2 (Per second) at 60W.

General mode:

The energy density (ED) / (fluence) of the proposed device: ≤39.8 J/cm^2 (Per second) is substantial equivalence with the predicate device, K242755 (VELAS Ⅱ-30B): 1.7~39.8 J/cm^2 (Per second) claims.

Comment 3 Power Density:

Physical therapy mode:

The power density of the proposed device: ≤6.2 W/cm^2, which is different to the predicate device, K242755 (VELAS Ⅱ-30A and VELAS Ⅱ-30B): 0.05~3.1 W/cm^2, but the power density of the proposed device will within the scope of predicate device, K121363 (Diowave 60W). This difference does not affect the safety and effectiveness of the device.

Power Density

PD = P/S*Duty W/cm^2

All other conditions being equal, the higher the output power, the higher the power density. At a maximum output power of 60W, the power density will be twice as high as at a maximum output power of 30W. While the Max. PD≤3.1 W/cm^2 at 30W, the Max. PD will ≤6.2 W/cm^2 at 60W.

General mode:

The power density of the proposed device: ≤39.8 W/cm^2 is substantial equivalence with the predicate device, K242755 (VELAS Ⅱ-30B): 1.7~39.8 W/cm^2 claims.

Comment 4 Spot Diameter:

Physical therapy mode:

The spot diameter of the proposed device: 4~5 cm, which is different to the predicate device, K242755: 3.5~5 cm, but the spot diameter of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The spot diameter of the proposed device: 5~6 mm, which is different to the predicate device, K242755: 4~5 mm, but the energy density (ED) / (fluence) and power density of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

Comment 5 Working Distance:

Physical therapy mode:

The working distance of the proposed device: 0 cm~2 cm for therapy handpiece 1; 2 cm~3 cm for therapy handpiece 2, which is different to the predicate device, K242755: 3~5 cm.

The working distance of proposed device is shorter because the therapy handpiece head has a length of 3cm. Therefore, the actual distance from the laser light source at the end of the laser output port to the treatment end is 3 cm~5 cm for therapy handpiece 1 which is identical with the predicate device: 3~5 cm; 5 cm~6 cm for therapy handpiece 2, a little longer:1cm than the working distance of predicate device: 3~5 cm, but the energy density(ED) / (fluence) and power density are all within the scope of what predicate device claims and it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

General mode:

The working distance of the proposed device is the same with the predicate device.

Comment 6 Operation mode:

Physical therapy mode:

The operation mode of the proposed device (CW, repeat pulse) is different to the predicate device (CW, single pulse, repeat pulse). but the operation mode of the proposed device is within the scope of what predicate device claims. This difference does not affect the safety and effectiveness of the device.

General mode:

The operation mode of the proposed device is the same with the predicate device.

Comment 7 Pulse width:

Physical therapy mode:

The pulse width of the proposed device: 50μs-1s, which is different to the predicate device, K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B): 10ms-1s.

The difference in pulse width range (specifically the extension to 50 μs) is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B). The expanded parameter range operates within the same thermal safety margins and is justified by the overlapping therapeutic effect of elevating tissue temperature.

General mode:

The pulse width of the proposed device is the same with the predicate device.

Comment 8 Pulse repetition rate:

Physical therapy mode:

The pulse repetition rate of the subject device: 1Hz-10KHz, which is different to the predicate device, K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B): 1Hz-50Hz.

The difference in pulse repetition rate: 1Hz-10KHz and 1Hz-50Hz is a technological modification that does not raise new questions of safety and effectiveness. The fundamental technology (infrared emission for topical heating) and the intended use remain unchanged from the predicate device K242755 (VELAS Ⅱ-30A, VELAS Ⅱ-30B).

General mode:

The pulse repetition rate of the proposed device is the same with the predicate device.

Comment 9 Treatment Methods:

Physical therapy mode:

The treatment methods of the subject device (Contact, Non-contact), which is different to the predicate device (Non-contact), but it meets the clinical needs. Contact mode is convenient for doctors to operate, which is more labor-saving. Moreover, the therapy handpiece head of therapy handpiece 1 has been evaluated and tested for biocompatibility as required, and the test results meet the requirements. This difference does not affect the safety and effectiveness of the device.

General mode:

The treatment methods of the proposed device are the same with the predicate device.

Comment 10 Applied Part:

Physical therapy mode:

The applied part of the proposed device are the same with the predicate device.

General mode:

The applied part of the subject device (Handpiece), which is different to the predicate device (Fiber), but it meets the clinical needs. The applied part: Handpiece and fiber have the same function of transmitting laser energy to the treatment area, but handpiece is convenient for doctors to operate. This difference does not affect the safety and effectiveness of the device.

Comment 11 Transmission system

The transmission system of the subject device (400μm fibers with metal protective armors), which is different to the predicate device (fibers of 600μm with SMA905 connector).

The transmission system only transmits laser energy. Although the optical fiber core diameter of optical fiber transmission system is different, but it meets the clinical needs. This difference does not affect the safety and effectiveness of the device.

Conclusion:

The indication for use of the subject device claimed by proposed device is the same with the predicate device.

The proposed device uses same diode lasers technology as that used by the predicates. The core output parameters of the proposed device are identical to the predicates. The differences only exist in such contents: output power, energy density (ED) / (fluence), power density, spot diameter, working distance, operation mode, pulse width, pulse repetition rate, treatment methods, applied part and transmission system, that all can be controlled in range of application. These differences do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use.

So, the proposed devices are Substantially Equivalent (SE) to existing legally marketed predicate devices.

Ⅶ PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Medical Diode Laser System.

- Verify the conformity of the proposed devices with the requirements of IEC60601-1: 2005, AMD1 2012, AMD2 2020 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance).

- Verify the conformity of the proposed devices with the requirements of IEC60601-1-2: 2014 (Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic compatibility).

- Verify the conformity of the proposed devices to IEC 60825-1: 2014 (Safety of laser products - Part 1: Equipment classification and requirements).

- Verify the performance of the proposed devices according to IEC 60601-2-22: 2019 (Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment).

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as an Enhanced Documentation level.

Mechanical and acoustic testing

It is not applicable.

Animal Study

It is not applicable.

Clinical Studies

It is not applicable.

Ⅷ CONCLUSIONS

The CureLight Medical diode laser systems are substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.