April 15, 2026

Shenzhen Kaiyan Medical Equipment Co., Ltd.
Alain Dijkstra
CEO
Bldg.#3 And Bldg.#5, 40th Of Fuxin Streey
Huaide Community Fuyong Town, Baoan District
Shenzhen, Guangdong 518103
China

Re: K260129
Trade/Device Name: Lumaflex Panel (ZLD-05, ZLD-05A, ZLD-05APro)
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI, OHS, ILY
Dated: January 16, 2026
Received: January 16, 2026

Dear Alain Dijkstra:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.04.15 22:04:47 -04'00'

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.	K260129

Please provide the device trade name(s).

Lumaflex Panel (ZLD-05, ZLD-05A, ZLD-05APro)

Please provide your Indications for Use below.

For Model ZLD-05:
- Mode 1:
The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
- Mode 2:
The Lumaflex Panel is intended for use in the treatment of full-face wrinkles.

- Mode 3:
The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
For Model ZLD-05A:
- Mode 1:
The Lumaflex Panel is intended for use in the treatment of full-face wrinkles.
- Mode 2:
The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
For Model ZLD-05APro:
- Mode 1:
The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
- Mode 2:
The Lumaflex Panel is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
- Model 3:
The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

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

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary of K260129

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Tel: 0755-82129361
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Contact Person (including title): Alain Dijkstra (CEO)
E-mail: regulation@kaiyanmedical.com

Distributor 1:
Distributor Name: Lumaflex LLC
Address: 382 NE 191ST Street, Suite 30327, Miami, FL33117, USA
Contact Person: John Graham Harper
Telephone No: +1 323 507 4005
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Application Correspondent:
Contact Person: Mr. Alain Dijkstra
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Tel: +86 755 82129361
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Date of the summary prepared: April 9, 2026

2. Subject Device Information

Trade Name: Lumaflex Panel

Model: ZLD-05, ZLD-05A, ZLD-05APRO

Medical specialty: Physical Medicine, General & Plastic Surgery

Regulation: 21 CFR 878.5400, 21 CFR 890.5500, 21 CFR 878.4810

Product Code: OLI(Class 2)-fat reducing low level laser, ILY (Class 2)-Lamp, Infrared, Therapeutic Heating, OHS (Class 2) - Light Based Over The Counter Wrinkle Reduction

3. Predicate Device Information

Predicate Device:

Sponsor: Biophotas INC
Trade Name: Biophotas Celluma CONTOUR
510(k) Number: K232977
Medical specialty: Physical Medicine
Regulation: 21 CFR 878.5400, 21 CFR 890.5500, 21 CFR 878.4810
Product Code: OLI(Class 2)-fat reducing low level laser, ILY (Class 2)-Lamp, Infrared, Therapeutic Heating, OHS (Class 2) - Light Based Over The Counter Wrinkle Reduction

Reference Device 1:
Sponsor: Light Tree Europe B.V.
Trade Name: Infrared Heat
510(k) Number: K223893
Medical specialty: General & Plastic Surgery
Regulation: 21 CFR 878.4810
Product Code: OHS (Class 2) - Light Based Over The Counter Wrinkle Reduction

Reference Device 2:
Sponsor: LED Intellectual Properties, LLC
Trade Name: LightStim Professional 2-Panel Light System
510(k) Number: K150098
Medical specialty: Physical Medicine
Regulation: 21 CFR 890.5500, 21 CFR 878.4810
Product Code: ILY (Class 2)-Lamp, Infrared, Therapeutic Heating
Associated Product Code(s): OHS (Class 2) - Light Based Over The Counter Wrinkle Reduction

Reference Device 3:
Sponsor: USA Laser Biotech Inc.
Trade Name: Lumix Ultra 1, Lumix Ultra 2, Lumix Ultra 3
510(k) Number: K161198
Medical specialty: Physical Medicine
Regulation: 21 CFR 890.5500
Product Code: ILY (Class 2)-Lamp, Infrared, Therapeutic Heating

4. Device Description

The Lumaflex Panel, model: ZLD-05, ZLD-05A and ZLD-05APro, is an over-the-counter light emitting diode (LED) device

For model ZLD-05, is an over-the-counter light emitting diode (LED) device that applies 630nm light for the purpose of reducing the circumference of the hips, waist, and thighs for aesthetic benefit, and emits 630nm and 850nm light to treat wrinkles and relieve pain.

For model ZLD-05A, used for treatment of full-face wrinkles, and pain relieve on the body by emitting LED red(630nm) and infrared(850nm) light.

For model: ZLD-05APro, is an over-the-counter light emitting LED red (630nm, 660nm) for the purpose of reducing the circumference of the hips, waist, and thighs for aesthetic benefit, and emits NIR (810nm, 850nm, 904nm and 1064nm) or RED+NIR (630nm, 660nm + 810nm, 850nm, 904nm and 1064nm) light to relieve pain.

For model ZLD-05:

The device can be controlled via the physical ON/OFF button on its controller. To turn the device on or off, press and hold the button for 2 seconds. When the device is on, a quick press of the same button starts the treatment. During treatment, pressing the button pauses the session; pressing it again resumes the treatment. Alternatively, for a more detailed interface, users can download the **LumaFlex** app. Connecting the device via Bluetooth through the app enables the selection of treatment modes and allows observation of the remaining treatment time.

For model ZLD-05APro:

The device can be controlled via the physical ON/OFF button on its controller. To turn the device on or off, press and hold the button for 2 seconds. When the device is on, a quick press starts the treatment (the default mode is Mode 3). During treatment, pressing the button pauses the session; pressing it again resumes the treatment. For enhanced control and monitoring, users can also connect the device to the **LumaFlex** app via Bluetooth. This allows for the selection of treatment modes and viewing of the remaining treatment time.

For model ZLD-05A:

The device features a single button for all operations. Press and hold to power the device on or off. Press the button shortly to switch between the available treatment modes. This model does not support Bluetooth connectivity or app control.

Each mode has been preset with the treatment time. When the treatment time is over, the equipment will automatically shut down.

The Lumaflex Panel components include a light panel, a controller, a charging cable, a short strap, a long strap, a cleaning cloth and goggles.

The device is powered by the controller. If the controller runs out of power, please use the charging cable provided by the manufacturer to charge the controller.

5. Indications for Use

For Model ZLD-05:

- Mode 1:
  The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
- Mode 2:
  The Lumaflex Panel is intended for use in the treatment of full-face wrinkles.
- Mode 3:
  The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

For Model ZLD-05A:

- Mode 1:
  The Lumaflex Panel is intended for use in the treatment of full-face wrinkles.
- Mode 2:
  The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle

and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

For Model ZLD-05APro:

- Mode 1:
  The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
- Mode 2:
  The Lumaflex Panel is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.
- Model 3:
  The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

6. Device Technological Characteristics

The Lumaflex phototherapy panel series consists of three models: ZLD-05, ZLD-05A and ZLD-05APro. This series of equipment is a non-prescription light-emitting diode (LED) device that emits specific wavelengths of red light and near-infrared light to relieve pain, treat wrinkles and reduce local body circumference. The following are the detailed technical characteristics of each model.

1) Power Supply and Controller

All models of the equipment are powered by an independent controller. The controller is equipped with a rechargeable battery. When the battery runs out, it needs to be charged using the dedicated charging cable provided by the manufacturer. The equipment is connected to the phototherapy panel through the controller to achieve power supply and control functions.

2) User Interface and Control Methods

There are differences in the user interface and control methods for different models:
ZLD-05 and ZLD-05APro: Users need to download the LumaFlex application and connect the device to their mobile phones via Bluetooth. The application interface allows users to select among three preset treatment modes and monitor the remaining treatment time in real time.
ZLD-05A: The device has only one physical button. Long press is used for turning on/off the device, and short press is used to switch treatment modes.

3) Treatment mode Characteristics

The spectral wavelengths emitted by each model vary depending on its intended use:
ZLD-05: It emits 630nm red light and 850nm near-infrared light.

- Mode 1(*Substantial Equivalence to K232977*): the 630nm light is used to reduce the circumference of the buttocks, waist, and legs to improve appearance.
- Mode 2(*Substantial Equivalence to K223893*): the combination of 630±20nm and 850±10nm light is used for treating wrinkles
- Mode 3(*Substantial Equivalence to K150098*): the combination of 630±20nm and 850±10nm light is used for relieving body pain.

ZLD-05A: It emits 630nm red light and 850nm near-infrared light。

- Mode 1(*Substantial Equivalence to K223893*): the combination of 630±20nm and 850±10nm light is used for treating wrinkles
- Mode 2(*Substantial Equivalence to K150098*): the combination of 630±20nm and 850±10nm light

is used for relieving body pain.

ZLD-05APRO: It emits red light within the range of 630nm, 660nm, 810nm, 850nm, 904nm, 1064nm

- Mode 1(*Substantial Equivalence to K232977*): the combination of 630nm and 660nm is used to reduce the circumference of the buttocks, waist, and legs to improve appearance.
- Mode 2(*510k Exempt*): the combination of 810nm, 850nm, 904nm, 1064nm light is used for relieving body pain.
- Mode 3(*510k Exempt*): the combination of 630nm, 660nm and 810nm, 850nm, 904nm, 1064nm light is used for relieving body pain.

7. Comparison to Predicate Devices

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Verdict
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Biophotas INC	Light Tree Europe B.V.	LED Intellectual Properties, LLC	USA Laser Biotech Inc.	--
Trade Name	Lumaflex Panel	Biophotas Celluma RESTORE	Infrared Heat	LightStim Professional 2-Panel Light System	LUMIX ULTRA 1 IR Lamp System; LUMIX ULTRA 2 IR Lamp System; LUMIX ULTRA 3 IR Lamp System	--
510(k) Number	K260129	K232977	K223893	K150098	K161198	--
Medical Specialty	Physical Medicine General & Plastic Surgery	Physical Medicine	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Regulation	21 CFR 878.5400, 21 CFR 890.5500, 21 CFR 878.4810	21 CFR 878.5400, 21 CFR 890.5500, 21 CFR 878.4810	21 CFR 878.4810	21 CFR 890.5500, 21 CFR 878.4810	21 CFR 890.5500	Same
Product code	OLI, ILY, OHS	OLI, ILY, OHS	OHS	ILY, OHS	ILY	Similar Note1
Regulation Class	II	II	II	II	II	Same

Intended use	**For Model ZLD-05:** - Mode 1: The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. - Mode 2: The Lumaflex Panel is intended for use in the treatment of full-face wrinkles. - Mode 3: The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating	The BIOPHOTAS Celluma CONTOUR is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The BIOPHOTAS Celluma CONTOUR is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The BioPhotas CONTOUR is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.	The Infrared Heat (Model: E0221) is intended to emit energy in the red and infrared spectrum for use in the treatment of full face wrinkles	The LightStim Professional 2-Panel Light System has two (2) interchangeable 2-Panel LED Systems, each mounted on a hands-free, fully articulating arms: System #1- emitting energy in the visible and IR spectrums intended for use in the treatment of full-face wrinkles. System #2 - emitting energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle	The LUMIX ULTRA IR Lamp Systems are intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.	Similar Note1

	for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. **For Model ZLD-05A:** - Mode 1: The Lumaflex Panel is intended for use in the treatment of full-face wrinkles. - Mode 2: The			spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.		

	Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. **For Model ZLD-05APro:**					

	- Mode 1: The Lumaflex Panel is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. - Mode 2: The Lumaflex Panel is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain,					

	arthritis, and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. - Mode 3: The Lumaflex Panel is intended to deliver heat in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain,					

	arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.					
Intended Location of Use	full body	full body	Face	Full body	Full body	Same
Wavelength	For model ZLD-05, ZLD-05A: Red: 630 nm +/- 20nm NIR: 850+/- 10nm; For model ZLD-05APro: 630nm 660nm, 810nm, 850nm, 904nm, 1064nm	Red: 640nm+/- 25nm (615-665nm) 880nm+/50nm (830nm – 930nm)	630nm 830nm+/- 20nm	Unknown * 605nm, 630nm, 660nm, and 855nm their cited predicate device.	650nm to 1064nm	Similar Note2
LED number	For model ZLD-05: 45 For model ZLD-05A: 45 For model ZLD-05APro: 50	Not available	30	1130 LEDs	Not available	Different Note 3
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Not available	Same
Intensity (mW/cm2)	For model ZLD-05:	640nm+/-25nm	30 mW/cm^2	65 mW/cm^2	Not available	Different Note 4

	- Mode 1: 4.2mW/cm^2 - Mode 2: 30 mW/cm^2 - Mode 3: 65mW/cm^2 For model ZLD-05A: - Mode 1: 30 mW/cm^2 - Mode 1: 65mW/cm^2 For model ZLD-05APro: - Mode 1: 4.2mW/cm^2 - Mode 2: 20 mW/cm^2 - Mode 3: 65mW/cm^2	(615-665nm): 4.2mW/cm^2 880nm+/50nm (830nm – 930nm): 0.7mW/cm^2				
Treatment protocol (Treatment time)	**For Model ZLD-05:** - Mode1: 30 minutes - Mode2: 10 minutes - Moed3: 15 minutes **For Model ZLD-05A:** - Mode1: 10 minutes - Mode2: 15 minutes **For Model ZLD-05APro:** - Mode1: 30	30 minutes	10 minutes everyday	Not available	Not available	Different Note 5

	minutes - Mode2: 15 minutes - Moed3: 10 minutes					
Control	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	Not available	Not available	Not available	Same

Comparison in Detail(s):

Note 1:

Although “Product code” and “Intended use” of subject device is a litter different from predicate device, the device has three modes, each corresponding to a different intended use. According to the summary of predicate device (*K232977*), same to reduce of circumference; It is similar to the reference device 1 (*K223893*), and is used to mode treat wrinkles on the entire face, and for mode function of relieving minor muscle and joint pain is similar to the reference device 2 (*K150098*) and reference device 3 (*K161198*). So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 2:

Although the “Wavelength” of the subject device is slightly different from the predicate device, the wavelength of the subject device is included in the wavelength range of the predicate device and reference devices. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 3:

Although the “LED number” of the subject device is slightly different from the predicate device, the main parameters that ultimately affect the safety and effectiveness of the device are the energy of treatment, and the light beads are evenly distributed, which does not affect the safety of the device. So even if there is a difference between the number of lamp beads and the predicate device, it is still acceptable.

Note 4:

Although the “Intensity” of the subject device is slightly different from the predicate device, the intensity of Mode 1of the subject device (model ZLD-05) is the same as those of predicate device (*K232977*), the intensity of Mode 2 of the subject device (model ZLD-05) is the same as those of reference device 1(*K223893*), and the energy values of Mode 3 of the subject device are(model ZLD-05) the same as those of reference device 2 (*K150098*). And, the intensity of Mode 1of the subject device (model ZLD-05A) is the same as those of reference device 1(*K223893*), and the Intensity of Mode 2 of the subject device are (model ZLD-05A) the same as those of reference device 2 (*K150098*).

For model ZLD-05APro, the intensity of mode 1 is the same as that of predicate device (*K232977*). The reason why the intensity of mode 2 is higher than that of predicate device is that our wavelength is 1064nm more than that of predicate device, and the intensity value needs to be calculated in combination with the treatment area. Therefore, the actual value of the subject device is higher than

that of predicate device. The intensity of mode 3 is the same as that of reference device 2 (*K150098*). And all of they conducted the electrical and electromagnetic compatibility safety tests by following the IEC 60601 series and IEC 62471 standards, the test results demonstrate the device meet the IEC 60601 series IEC 62471 standards' requirements. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 5:

Although the "Treatment time" of the subject device is slightly different from the predicate device, the treatment time of mode 1 of the subject device(model ZLD-05, ZLD-05APro) is the same as those of predicate device, the treatment time of mode 2 of the subject device(model ZLD-05) and mode 1 of the subject device (model ZLD-05A) are the same as those of reference device 1; For Mode 3 of the subject device (model ZLD-05), mode 2 of the subject device (model ZLD-05A) and mode 2, 3 of the subject device (model ZLD-05APro), although there is no predicate device for direct comparison, it is a 510k Exempt functional mode, and its duration (15 minutes) is less than the 30-minute treatment time of predicate device. This is because our device incorporates a 1064nm wavelength, which is more than that of predicate device, allowing for a shorter treatment duration. And all of they conducted the electrical and electromagnetic compatibility safety tests by following the IEC 60601 series and IEC 62471 standards, the test results demonstrate the device meet the IEC 60601 series IEC 62471 standards' requirements. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

8. Test Summary

Lumaflex Panel (Model: ZLD-05, ZLD-05A, ZLD-05APro) has been evaluated the safety and performance by lab bench testing as following:

8.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance --Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- 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.
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.

2) Usability Testing

Usability testing was conducted on the Lumaflex Panel (Model: ZLD-05, ZLD-05A and ZLD-05APro)

3) 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 a "Basic Documentation Level", since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Cybersecurity

Cybersecurity software documentation was created for subject Lumaflex Panel device according to FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued on April 9, 2026.

8.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

9. Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K232977