May 4, 2026

Shenzhen Kaiyan Medical Equipment Co., Ltd.
Alain Dijkstra
Bldg.#3 And Bldg.#5, 40th Of Fuxin St., Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Shenzhen, Guangdong 51803
China

Re: K260688
Trade/Device Name: Sculpt LED Belt (HY-150A/HY-150B/HY-200A/HY-200B/HY-420A/HY-200D/HY-200C)
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI, ILY
Dated: March 3, 2026
Received: March 3, 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: 2026.05.04 14:38:06 -04'00'

Tanisha L. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260688

Device Name
Sculpt LED Belt
Models: HY-150A/HY-150B/HY-200A/HY-200B/HY-420A/HY-200D/HY-200C

Indications for Use *(Describe)*
For model HY-150A/HY-150B/HY-200A/HY-200B/HY-420A:
M1 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
M2 and M3 are intended to deliver heat in the Red+IR 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 HY-200D/HY-200C
M3 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI)up to 40 kg/m2.
M1 and M2 are intended to deliver heat in the Red,IR 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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement 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
Contact Person (including title): Alain Dijkstra (CEO)
Tel: +86-135-10378748
Fax: +86-755-25024651
E-mail: registrar01@kaiyanmedical.com

Application Correspondent:

Contact Person: 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
Fax: +86 755 25024651
Email: registrar01@kaiyanmedical.com

2. Subject Device Information:

Trade Name: Sculpt LED Belt, Model: HY-150A/HY-150B/HY-200A/HY-200B/HY-420A/HY-200D/HY-200C
Classification Name: Low Level Laser System For Aesthetic Use
Review Panel: General & Plastic Surgery
Product Code: OLI, ILY
Regulation Number:21 CFR 878.5400,21 CFR 890.5500
Regulation Class: II

3. Predicate Device Information

Energy Lounger(TY-01) under K241947 cleared by Shenzhen Kaiyan Medical Equipment Co.,Ltd
Biophotas Celluma CONTOUR under K232977 cleared by Biophotas Inc
Contour Light (CL-100) under K243854 cleared by Contour Research, LLC
Contour Light (CL-100) under K202955 cleared by Contour Research, LLC
Erchonia® Emerald Laser(Model# SHL) under K192544 cleared by Erchonia Corporation
Reference: Cellulize under K180338 cleared by Ward Photonics LLC

4. Device Description

The Sculpt LED Belt is a wearable device used for treatment of reduction of circumference of body and temporary relief of minor muscle and joint pain by emitting LED red(630nm) and infrared(850nm+940nm) or green(532nm),red(630nm) and infrared(850nm). The device is powered by a rated adapter or rechargeable lithium battery, and it has instruction manual and adapter/charging cable.

The recommend treatment time is 10min per area, when the user choose the mode and treatment time and the treatment automatically completed after 10/20minutes.If you need to continue treatment, simply turn on the device again.

5. Intended Use / Indications for Use

For model HY-150A/HY-150B/HY-200A/HY-200B/HY-420A:
M1 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
M2 and M3 are intended to deliver heat in the Red+IR 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 HY-200D/HY-200C
M3 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI)up to 40 kg/m^2.
M1 and M2 are intended to deliver heat in the Red,IR 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. Model difference description

	HY-150A	HY-150B	HY-200A	HY-200B	HY-420A	HY-200D	HY-200C
Battery equipped	No	Yes	No	Yes	No	Yes	No
Accessory	Adapter	USB cable	Adapter	USB cable	Adapter	USB cable	Adapter
Indicator	Mode indicator	Mode indicator and charging indicator	Mode indicator	Mode indicator and charging indicator	Mode indicator	Mode indicator and charging indicator	Mode indicator
Charging/adapter on work	Yes	No	Yes	No	Yes	No	Yes

Intended use	M1 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. M2 and M3 are intended to deliver heat in the Red+IR 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.	M3 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI)up to 40 kg/m^2. M1 and M2 are intended to deliver heat in the Red,IR 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
Wavelength	630nm,850nm,940nm	532nm,630nm,850nm
Mode	Mode 1: 630nm--weight loss Mode 2: 630nm+850nm--pain relief temporally Mode 3: 630nm+850nm+940nm--pain relief temporally	Mode 1: 850nm--pain relief temporally Mode 2: 630nm+850nm--pain relief temporally Mode 3: 532nm--weight loss
Irradiance	M1 (630nm): 4.2mw/cm^2 M2(630nm+850nm):18.7 mw/cm^2 M3(630+850+940nm):60 mw/cm^2	630nm:4.2mW/cm^2 850nm:0.7mW/cm^2 532nm:95 mW/cm^2

7. Comparison to predicate devices

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

Elements of Comparison	Subject device	Predicate device 1 (K241947)	Predicate device 2 (K232977)	Predicate device 3 (K243854)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	Biophotas Inc	Contour Research, LLC	--

Elements of Comparison	Subject device	Predicate device 1 (K241947)	Predicate device 2 (K232977)	Predicate device 3 (K243854)	Remark
510 (K) Number	Applying	**K241947**	**K232977**	**K243854**	--
Device Name	Sculpt LED Belt	Energy Lounger	Biophotas Celluma CONTOUR	Contour Light	--
Model	HY-150A; HY-150B; HY-200A; HY-200B; HY-420A;	TY-01	/	CL-100	--
OTC/Rx	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Same
Product Code	OLI+ILY	OLI+ILY+OHS	OLI, ILY, OHS	OLI+ILY	Same
Regulation Number	21 CFR 878.5400, 21 CFR 890.5500	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 878.5400, 21 CFR 890.5500	Same
Indications for Use / Intended use	M1 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. M2 and M3 are intended to deliver heat in the Red+IR 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.	M1 is used to reduce the circumference of the hips, waist and thighs and is indicated for use as a non-invasive dermatological. M2 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles. M3 is intended to emit 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 spasm, the temporary increase in local blood circulation,	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 Contour Light CL-100 device is intended for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips,waist, and thighs. The Contour Light CL-100 device is indicated to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain,muscle spasm, and pain and stiffness associated with arthritis, for promoting relaxation of the muscle tissue, and to temporarily increase local blood	Same

Elements of Comparison	Subject device	Predicate device 1 (K241947)	Predicate device 2 (K232977)	Predicate device 3 (K243854)	Remark
		and the temporary relaxation of muscles.	The BioPhotas Celluma CONTOUR is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.	circulation.	
Power Source	For HY-150B/HY-200B lithium battery:3.7V, 6000mAh,22.2Wh Charging cable:100-240Va.c., 50/60Hz; 5Vd.c, 2A For HY-150A/HY-200A/HY-420A Adapter:100-240Va.c., 50/60Hz; 12V~ 3A, 36W	Input: 100-240Vac 50/60Hz, 30.5A/115Vac, 16A/230Vac Output: 12Vdc, 240A	90-264 VAC	Not published	Similar (Note 1)
Irradiance source	LED	LED	LED	LED	Same
LED wavelength	630nm 850nm 940nm；	635nm 850nm 940nm	Red: 640nm±25nm (615-665nm) 880nm ±50nm (830nm-930nm)	635nm 880nm	Similar (Note 2)
Irradiances(mw/cm^2)	M1 (630nm): 4.2mw/cm^2 M2 (630nm+850nm): 18.7 mw/cm^2 M3 (630+850+940nm): 60 mw/cm^2	M1 (630nm): 4.2mw/cm^2 M2 (630nm+850nm): 18.7 mw/cm^2 M3 (630+850+940nm): 60 mw/cm^2	640:4.2mW/cm^2 880:0.7mW/cm^2	70mW/cm^2 total	Similar (Note 2)
Treatment Time	10/20mins per treatment	M1:20min M2: 20min M3: 30min	30minutes	0 -30 minutes	Similar (Note 3)

Elements of Comparison	Subject device	Predicate device 1 (K241947)	Predicate device 2 (K232977)	Predicate device 3 (K243854)	Remark
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-83 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-2	unknown	Same
Biocompatibility	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23	ISO10993-5 ISO10993-10 ISO 10993-23	unknown	Same

Comparison in Detail(s):

Note 1:
The power supply for the subject device is a little different from that of the predicate device, however the lithium battery of the subject device has been tested under standard IEC 62133-2,and the adapter has passed the IEC60601-1, so this difference should not raise any safety/effectiveness issues.

Note 2:
The wavelength of the subject device is included in the predicate devices.
And the Irradiance of subject device is similar with predicate device 1,and the range of irradiance is included in the predicate devices.
And the irradiance also passed the safety test IEC60601-1; so it can be concluded that the subject device can achieve the same treatment effect (reduction of circumference of body and temporary relief of minor muscle and joint pain)as the predicate devices. In addition, all of them have passed the tests of IEC 60601-1,IEC 60601-1-11 and IEC 60601-2-83/57, these differences will not raise any new safety or effectiveness issues.

Note 3:
The treatment time of subject device is similar with predicate devices and is included in predicate devices.

Elements of Comparison	Subject device	Predicate device 1 (K202955)	Predicate device 2 (K232977)	Predicate device 3 (K192544)	Reference device (K180338)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Contour Research, LLC	Biophotas Inc	Erchonia Corporation	Ward Photonics LLC	--
510 (K) Number	Applying	**K202955**	**K232977**	**K192544**	**K180338**	--

Elements of Comparison	Subject device	Predicate device 1 (K202955)	Predicate device 2 (K232977)	Predicate device 3 (K192544)	Reference device (K180338)	Remark
Device Name	Sculpt LED Belt	Contour Light CL-100	Biophotas Celluma CONTOUR	Erchonia® Emerald Laser	Cellulize	--
Model	HY-200D; HY-200C	/	/	SHL	/	--
OTC/Rx	OTC	Rx	OTC	Rx	Rx	Same
Regulation Class	Class II	Class II	Class II	Class II	Class II	Same
Product Code	OLI+ILY	OLI+ILY	OLI, ILY, OHS	OLI	OLI	Same
Regulation Number	21 CFR 878.5400, 21 CFR 890.5500	878.5400, 890.5500	21 CFR 878.5400 21 CFR 890.5500 21 CFR 878.4810	21 CFR 878.5400	21 CFR 878.5400	Same

Elements of Comparison	Subject device	Predicate device 1 (K202955)	Predicate device 2 (K232977)	Predicate device 3 (K192544)	Reference device (K180338)	Remark
Indications for Use / Intended use	M3 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI)up to 40 kg/m^2. M1 and M2 are intended to deliver heat in the Red,IR 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 Contour Light CL-100 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The Contour Light CL-100 is intended to deliver heat in the IR 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 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 Celluma 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 Erchonia® Emerald(Model#: SHL) Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI)up to 40 kg/m^2	Cellulize is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.	Same

Elements of Comparison	Subject device	Predicate device 1 (K202955)	Predicate device 2 (K232977)	Predicate device 3 (K192544)	Reference device (K180338)	Remark
Power Source	For HY-200D lithium battery:3.7V, 6000mAh,22.2Wh Charging cable:100-240Va.c., 50/60Hz; 5Vd.c, 2A For HY-200C Adapter:100-240Va.c., 50/60Hz; 12V~ 3A, 36W	Not available	90-264 VAC	100-120VAC, 50/60Hz	100-120VAC, 3A,50/60Hz	Similar (Note 1)
Irradiance source	LED	LED	LED	Laser	LED	Same
LED wavelength	532nm; 630nm; 850nm	635nm 880nm	Red: 640nm±25nm (615-665nm) 880nm ±50nm (830nm-930nm)	522nm to 542nm	532±3nm	Similar (Note 2)
Irradiances(mw/cm^2)	630nm:4.2mW/cm^2 850nm:0.7mW/cm^2 532nm:95mW/cm^2	4.1mW/cm^2， 0.5mW/cm^2	640:4.2mW/cm^2 880:0.7mW/cm^2	16mW±2mW (Power measured at aperture)①	95.14mW/cm^2	Similar (Note 2)
Treatment Time	10/20mins per treatment	30minutes	30minutes	0-30mintues	Each treatment is four 8-minute exposures (front, back,left, and right), 32-minute total per treatment session.	Similar (Note 3)

Elements of Comparison	Subject device	Predicate device 1 (K202955)	Predicate device 2 (K232977)	Predicate device 3 (K192544)	Reference device (K180338)	Remark
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-83 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-2	Compliant with IEC 60601- 1, IEC 60601-1-2	Compliant with IEC 60601- 1, IEC 60601-1-2 IEC 60825-1	unknown	Same
Biocompatibility	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23	unknown	ISO10993-5 ISO10993-10 ISO 10993-23	NA	unknown	Same

①Remark:Since this is the power of a single laser light, the area of a single light cannot be known, and thus the irradiance cannot be calculated.

Comparison in Detail(s):

Note 1:

The power supply for the subject device is a little different from that of the predicate device, however the lithium battery of the subject device has been tested under standard IEC 62133-2,and the adapter has passed the IEC60601-1, so this difference should not raise any safety/effectiveness issues.

Note 2:

The wavelength of the subject device is included in the predicate devices.

And the Irradiance of subject device is similar with predicate devices,and the range of irradiance is included in the predicate devices. And the irradiance also passed the safety test IEC60601-1; so it can be concluded that the subject device can achieve the same treatment effect (reduction of circumference of body and temporary relief of minor muscle and joint pain)as the predicate devices. In addition, all of them have passed the tests of IEC 60601-1,IEC 60601-1-11 and IEC 60601-2-83, these differences will not raise any new safety or effectiveness issues.

Note 3:

The treatment time of subject device is similar with predicate devices and is included in predicate devices.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device 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
- 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 60601-2-83:2019+AMD1:2022 Edition 1.1 Medical Electrical Equipment - Part 2-83- Particular requirements for the basic safety and essential performance of home light therapy equipment.
- 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.
- IEC 62133-2:2017+AMD1:2021 Edition1.1 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

2) Biological Compatibility Statement

The component of the Sculpt LED Belt (Model: HY-150A/HY-150B/HY-200A/HY-200B/HY-420A/HY-200D/HY-200C) has been conformed to ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

3) Software verification and validation

Software verification and validation testing was conducted and documentation 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 is considered as a "Basic Level Documentation", since a malfunction of or a latent design flaw in the Software Device leads to an erroneous diagnosis or a delay in the delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation

The subject device has undergone human factors and usability engineering testing to identify representative users from its intended OTC market. A Use-Related Risk Analysis (URRA) was created to detail the risks in the usage of this device. With consultation from clinically trained professionals, a Health Assessment Questionnaire (HAQ) was developed for the purpose of screening prospective users. During this screening, no contraindicated users opted to use the device. Finally, the study confirmed with 30 self-selected users that the device instructions were sufficiently clear to pass the URRA and allow patients to self-select for their intended use. These results were confirmed with a graded examination of the users, which all passed.

7.2 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.

8. Date of the summary prepared: April 27, 2026

9. <u>Final Conclusion</u>

The subject device is equally safe, effective, and performs as well or better than the legally marketed predicated devices K241947,K232977,K243854,K202955, and K192544.