October 3, 2025

Senbitec Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group LLC
7505 Fannin St Suite 610
Houston, Texas 77054

Re: K242946
Trade/Device Name: Hestia (L200-A)
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: GEX
Dated: October 2, 2025
Received: October 2, 2025

Dear Dave Kim:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 2025.10.03 16:10:10 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242946

Device Name

HESTIA (L200-A)

Indications for Use *(Describe)*

The HESTIA is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary surgery.

The HESTIA is indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary surgery as follows:

[Dermatology & Plastic Surgery]
Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, &/or treatment of:
hemangiomas (including Buccal and port wine);
removal of small skin tumors;
milia;
basal and squamous cell carcinoma;
tricoepitheliomas;
syringoma

Laser incision &/or excision of soft tissue for the performance of blepharoplasty.

Laser incision &/or excision of soft tissue for the creation of recipient sites for hair transplantation

[Podiatry]
Laser ablation, vaporization &/or excision of soft tissue for the reduction, removal, &/or treatment of:
verrucae vulgares/plantar (warts);

Laser ablation, vaporization and/or excision in podiatry for complete and partial matrixectomy;

[Otolaryngology (ENT)]
Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for treatment of:
polypectomy of nose and nasal passages;

[Gynecology]
Laser incision, ablation and/or vaporization of soft tissue in GYN for treatment of:
condyloma acuminata, including cervical, genital, vulvar and perineal;
hemangiomas

[Genitourinary]
Incision/excision and vaporization of soft tissue in genitourinary procedures.
Applications include:

condyloma;
phimosis;

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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Section 17 – 510(k) Summary
K242946

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92
Date: September 20, 2024

I. 510K Applicant / Submitter:

Senbitec Co., Ltd.
304, 46-24 LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
Tel: +82-31-477-7964
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II. Submission Contact Person (Primary Correspondent Person)

Mr. Dave Kim
Mtech Group LLC
7505 Fannin St. Suite 610, Houston, TX 77054
Tel: 713-467-2607
Email: davekim@mtechgroupllc.com

III. Subject Device

- Trade/Proprietary Name: HESTIA (Model Name: L200-A)
- 510(k) Number: K242946
- Common Name: Powered Laser Surgical Instrument
- Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
- Regulation: 21 CFR 878.4810
- Product Code: GEX

IV. Predicate Device & Reference Device

A. Predicate Device

- Proprietary Name: Lumenis Ultrapulse Encore and Carbon Dioxide Surgical Laser and Delivery Device Accessories
- 510(k) Number: K022060
- Common Name: Powered Laser Surgical Instrument
- Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
- Regulation: 21 CFR 878.4810
- Product Code: GEX

B. Reference Device

- Proprietary Name: Azure
- 510(k) Number: K231514
- Common Name: Powered Laser Surgical Instrument
- Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
- Regulation: 21 CFR 878.4810

- Product Code: GEX

V. Description:

This surgical laser is used for an operation to destroy and remove tissue by transmitting the optical energy of 10,600nm in wavelength, which is generated from the CO_2 Laser tube, through a hand-piece. This device is composed of a hand-piece through which laser is output to the main body, articulated arm, foot switch, and power cord.

VI. Indications for Use

The HESTIA is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary surgery.

The HESTIA is indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary surgery as follows:

Dermatology & Plastic Surgery

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, &/or treatment of:
hemangiomas (including Buccal and port wine);
removal of small skin tumors;
milia;
basal and squamous cell carcinoma;
tricoepitheliomas;
syringoma

Laser incision &/or excision of soft tissue for the performance of blepharoplasty.

Laser incision &/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

Laser ablation, vaporization &/or excision of soft tissue for the reduction, removal, &/or treatment of:
verrucae vulgares/plantar (warts);

Laser ablation, vaporization and/or excision in podiatry for complete and partial matrixectomy;

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for treatment of:
polypectomy of nose and nasal passages;

Gynecology

Laser incision, ablation and/or vaporization of soft tissue in GYN for treatment of:
condyloma acuminata, including cervical, genital, vulvar and perineal;
hemangiomas

Genitourinary

Incision/excision and vaporization of soft tissue in genitourinary procedures.
Applications include:

condyloma;
phimosis;

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

[Hestia (K242946) vs. Lumenis Ultrapulse Encore and Carbon Dioxide Surgical Laser and Delivery Device Accessories (K022060)]

The subject device [Hestia] is substantially equivalent to predicate device [Lumenis Ultrapulse Encore and Carbon Dioxide Surgical Laser and Delivery Device Accessories (K022060)]. The following comparison table is presented to demonstrate substantial equivalence.

The differences of two devices include “max. power (W)”, “energy (J)”, “frequency (Hz)”, “spot size”, “pulse width”. A direct comparison is difficult because the values [“max. power (W)”, “energy (J)”, “frequency (Hz)”, “spot size”, “pulse width”] of the predicate device (Lumenis Ultrapulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories, K022060) is unknown. As this cannot be determined from the predicate device alone, an additional reference device has been selected for comparison purposes.

Among the comparison items, "Patient contact material", "sterilization", "single-use/reusable" of the predicate device (Lumenis Ultrapulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories, K022060) is also unknown.
However, not knowing this information will not affect the safety or effectiveness of the subject device (Hestia), as biocompatibility testing, user sterilization and reprocessing validation were conducted on it.

	Subject device	**Predicate Device**	**Remark**
Manufacturer	SENBITEC Co., Ltd.	Lumenis Inc.	-
Common Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	
Regulation Name	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	-
Brand Name	Hestia	Lumenis Ultrapulse Encore and Carbon Dioxide Surgical Laser and Delivery Device Accessories	-
Device Class	Class II	Class II	-
CFR Regulation	21 CFR 878.4810	21 CFR 878.4810	-
Product Code	GEX	GEX	-
510(K) Number	K242946	K022060	-
Indication for Use	The HESTIA is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary surgery. The HESTIA is indicated for use in the performance of specific surgical applications in aesthetic	Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers (and their delivery accessories) are used to deliver light energy and are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including	Substantial Equivalence

	Subject device	Predicate Device	Remark
	(dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary.	laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. In addition, the Lumenis UltraPulse Encore Carbon Dioxide Surgical Lasers are safe and effective when indicated for use in specific surgical applications in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.	
Laser Type	Carbon Dioxide (CO_2)	Carbon Dioxide (CO_2)	Same as predicate
Wave length (μm)	10.6 μm	10.6 μm	Same as predicate
Max. Power (W)	40 W	Not Publicly Available	Unknown
Energy (mJ)	40 W(CW mode) 1mJ ~ 150mJ(U-Pulse Mode)	Not Publicly Available	Unknown
Frequency (Hz)	1Hz ~ 1,000Hz	Not publicly available	Unknown
Spot Size	-. Surgical (F:50㎜) : Ø0.25㎜ ± 20% -. Surgical (F:100㎜) : Ø0.40㎜ ± 20%	Not Publicly Available	Unknown
Pulse Width	150μs ~ 5000μs	Not publicly available	Unknown
Aiming beam	-. Medium used: Diode (InGaAIP) -. Power: MAX 3.0mW -. Wavelength: 655nm	Not Publicly Available	Substantial Equivalence
Exposure Mode	CW, Single, Pulse and U-Pulse	CW, Ultra Pulse and SurgiTouch	Substantial Equivalence
Patient Contact Material	Guide Bar : Aluminum Alloy Extruded Shapes -A6061	Not publicly available	Substantial Equivalence
Sterilization	User Moist Heat (Only Guide Bar)	Not publicly available	Substantial Equivalence

	Subject device	Predicate Device	Remark
Single-use/Reusable	Reusable (Only Guide Bar)	Not publicly available	Substantial Equivalence
Type of Use	Prescription Use	Prescription Use	Same as predicate

[Hestia (K242946) vs. Azure (K231514)]

The subject device [Hestia] is substantially equivalent to the reference device *[*Azure (K231514)*]*. The following comparison table is presented to demonstrate substantial equivalence.

	Subject device	Reference Device	Remark
Manufacturer	SENBITEC Co., Ltd.	DAESHIN ENTERPRISE CO., Ltd.	-
Common Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	
Regulation Name	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology	-
Brand Name	Hestia	Azure	-
Device Class	Class II	Class II	-
CFR Regulation	21 CFR 878.4810	21 CFR 878.4810	-
Product Code	GEX	GEX	-
510(K) Number	K242946	K231514	-
Indication for Use	The HESTIA is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary surgery. The HESTIA is indicated for use in the performance of specific surgical applications in aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, and genitourinary.	Azure(DS-22CO) is intended for use in non-fractionated mode for Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues in Dermatology, Plastic surgery, General Surgery, Gynecology, Neurosurgery, and in Podiatry.	Substantial Equivalence
Laser Type	Carbon Dioxide (CO_2)	Carbon Dioxide(CO_2)	Same as reference
Wave length (μm)	10.6 μm	10.6 μm	Same as reference
Max. Power (W)	40 W	30W	Substantial Equivalence
Energy (mJ)	40 W(CW mode) 1mJ ~ 150mJ(U-Pulse Mode)	30W (CW mode) 15000mJ (Ultra mode)	Substantial Equivalence
Frequency (Hz)	1Hz ~ 1,000Hz	1Hz~500Hz	No significant difference

	Subject device	Reference Device	Remark
Spot Size	-. Surgical (F:50㎜): Ø0.25㎜ ± 20% -. Surgical (F:100㎜): Ø0.40㎜ ± 20%	-. Surgical (F:50㎜): 0.20㎜ -. Surgical (F:100㎜): 0.40㎜ -. Zoom Handpiece: 0.2~1.0㎜	Substantial Equivalence
Pulse Width	150㎲ ~ 5000㎲	60㎲~900㎲	No significant difference
Aiming beam	-. Medium used: Diode (InGaAIP) -. Power: MAX 3.0mW -. Wavelength: 655nm	-. Medium used: Diode (InGaAIP) -. Power: MAX 5.0mW -. Wavelength: 650nm	Substantial Equivalence
Exposure Mode	CW, Single, Pulse and U-Pulse	CW, Ultra mode	Substantial Equivalence
Patient Contact Material	Guide Bar : Aluminum Alloy Extruded Shapes -A6061	Not publicly available	Substantial Equivalence
Sterilization	User Moist Heat (Only Guide Bar)	Not publicly available	Substantial Equivalence
Single-use/Reusable	Reusable (Only Guide Bar)	Not publicly available	Substantial Equivalence
Type of Use	Prescription Use	Prescription Use	Same as reference

The following information on the reference device [Azure (K231514)] has been compared with the subject device: "maximum power (W)", "energy (J)", "frequency (Hz)", "spot size" and "pulse width". There is a slight difference between the subject device (Hestia) and the reference device [Azure (K231514)] for the items 'frequency (Hz)' and 'pulse width'.

These are optional specifications that users can adjust as per their requirements and do not constitute special functions.

The subject device (Hestia) was also demonstrated in the performance tests for safety and effectiveness, and all test criteria were met.

VIII. Performance Data

Non-clinical bench tests were performed as followings:

ISO 14971 Third Edition 2019-12 [Rec. Number 5-125]
Medical devices - Application of risk management to medical devices

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION [Rec. Number 19-49]
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 60601-1-2 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION [Rec. Number 19-36]
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-2-22 Edition 3.0 2012-10 [Rec. Number 12-356]

Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION [Rec. Number 5-132]
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION [Rec. Number 5-129]
Medical devices - Part 1: Application of usability engineering to medical devices

IEC 60825-1 Edition 2.0 2007-03 [Rec. Number 12-273]
Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION [Rec. Number 13-79]
Medical device software - Software life cycle processes

ISO 10993-1 Fifth edition 2018-08 [Rec. Number 2-258]
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Third edition 2009-06-01 [Rec. Number 2-245]
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 Fourth edition 2021-11 [Rec. Number 2-296]
Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-11 Third edition 2017-09 [Rec. Number 2-255]
Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ISO 10993-23 First edition 2021-01 [Rec. Number 2-291]
Biological evaluation of medical devices - Part 23: Tests for irritation

ISO 17665 First edition 2024-03 [Rec. Number 14-601]
Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17664-1 First edition 2021-07 [Rec. Number 14-578]
Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices

System testing (e.g., Energy Measurements, Safety Controls, Working Beam, aiming beam)

Along with the above tests, Electromagnetic Compatibility and Electrical Safety, Usability, Performance, and software validation were also conducted. None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazard.

X. Conclusions:

Based on the information provided in this premarket notification, **Senbitec Co., Ltd**. concludes that the **HESTIA (L200-A)** is substantially equivalent to the predicate device as described herein in safety and effectiveness.

The HESTIA has the same intended use and similar indications for use as its predicate device, **Lumenis Ultrapulse Encore and Carbon Dioxide Surgical Laser and Delivery Device Accessories (K022060)**. Further, the HESTIA has very similar technological characteristics and principles of operation as its predicate device, **Lumenis Ultrapulse Encore and Carbon Dioxide Surgical Laser and Delivery Device Accessories (K022060)**. The minor technological differences between the subject and the predicate devices do not raise different questions of safety or effectiveness. Performance testing of the device has demonstrated that the device performs as intended and thus, is substantially equivalent.