



July 2, 2025

Micro-Energy Medical Technology Co., Ltd  
Danning Zhu  
Registered Engineer  
Section B4301, B4701 and B4901, No. 13, Baolan Road  
Kengzi Street, Pingshan District  
Shenzhen, Guangdong 518118  
China

Re: K251049

Trade/Device Name: SurgiLight 1470 Diode Laser System (Model:Halo)

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: April 3, 2025

Received: April 3, 2025

Dear Danning Zhu:

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](mailto: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: 2025.07.02  
19:36:22 -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

510(k) Number (if known)  
K251049

Device Name  
SurgiLight 1470 Diode Laser System (ModelHalo)

### Indications for Use (Describe)

The SurgiLight 1470 Diode Laser System (Model: Halo) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux.

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.

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# 510(k) Summary

Date Prepared: July 2<sup>nd</sup>, 2025

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

## 1. Submitter's Information

Name of Sponsor: Micro-Energy Medical Technology Co., Ltd.  
Address: Section B4301, B4701 and B4901 No.13, Baolan Road,  
Kengzi Street, Pingshan District, Shenzhen, China

Contact Name: Elly Xu  
Telephone No.: +8613823755713  
Fax No.: +8613823755713  
Email Address.: sha.x@micro-energy.com  
Submission Number: K251049

## 2. Correspondent's Information

Company Name: Micro-Energy Medical Technology Co., Ltd.  
Correspondent Name: Danning Zhu  
Telephone No.: +8613580568872  
Email Address: danning.z@micro-energy.com

## 3. Trade Name, Common Name, Classification

Trade Name:	SurgiLight 1470 Diode Laser System
Common Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Model:	Halo
Classification Name:	Powered Laser Surgical Instrument
Product Code:	GEX
Classification Panel:	General & Plastic Surgery

Device Class:	II
Classification Regulation:	21 CFR 878.4810

**4. Identification of Predicate Device(s)**

The identified predicates within this submission are as follows:

Predicate Device 1:	510(k) number: K240644 Trade name: Medical Diode Laser Product code: GEX
Predicate Device 2:	510(k) number:K152722 Trade name:neoV980&neoV1470 Diode Lasers Product code: GEX

**5. Description of the Device**

The SurgiLight 1470 Diode Laser System (model: Halo) incorporates a 1470nm wavelength Gallium Arsenide (GaAs) diode laser for producing its therapeutic effects. The device also incorporates a red (650nm) aiming beam diode to indicate the area to be irradiated by the laser beam. The device is composed of the main unit, footswitch, a power cord and remote interlock components. The device incorporates an LCD touchscreen for the device user to set output parameters and for control of the device. The device transmits the laser output via optical fibers with SMA905 connectors.

**6. Intended Use/Indication for Use**

The SurgiLight 1470 Diode Laser System (Model: Halo) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux.

**7. Technological Characteristics**

The SurgiLight 1470 Diode Laser System (model:Halo) uses the same technology that is utilized in the predicate device. A comparison of technological characteristics is provided in the following table:

Item	Subject device (K251049)	Predicate device (K240644)	Predicate device (K152722)	Comparison
Product Code	GEX	GEX	GEX	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	II	Same
Device Name	SurgiLight 1470 Diode Laser System	Medical Diode Laser	neoV980&neoV1470 Diode Lasers	NA
Device Model	Halo	S1 Pro	neoV980&neoV1470 Diode Lasers	NA(Only compare the parameters at a wavelength of 1470)
Manufacturer	Micro-Energy Medical Technology Co., Ltd.	Wuhan Pioon Technology Co.,Ltd.	G.N.S NEO LASER LTD.	NA
Intended Use/Indication for Use	The SurgiLight 1470 Diode Laser System (Model: Halo) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and	The Medical Diode Laser(Model:S1Pro)is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery,	The neoV980 & neoV1470 Diode Lasers, (and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties	Same

		Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux.	Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: S1Pro) is further indicated for laser assisted lipolysis.	including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation, and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux.	
Target Population		Adult	Adult	Adult	Same
Laser Type		Diode laser	Diode laser	Diode laser	Same
Therapeutic	Maximum Laser Output Power	12 W	12w	10 W	Same as the predicate device(K240644), Similar with the predicate device(K152722)
	Wave Length	1470nm	1470nm	1470nm	Same

Laser Technical Features	Pulse Width	5 ms - 9,000 ms	10ms-25s	100µs-30s	Similar with the predicate device(K240644), within the scope of predicate device(K152722) Note01
	Repetition Rate	0.06HZ-100HZ	0-50HZ	0.02 Hz to 5,000 Hz	Similar with the predicate device(K240644), within the scope of predicate device(K152722) Note02
	Working Mode	Continuous Wave (CW),Single-Pulse and repeated plus	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Same
	Laser Beam Transmission Mode	fiber	fiber	fiber	Same
	Laser Level	Level 4	Level 4	Level 4	Same
Aiming Beam (light) Technical Features		Visible red laser Power:<2.6mW Wave Length:650nm adjustable brightness.	Visible red laser Power:<2mW Wave Length:650nm adjustable brightness.	Green 532nm (<5mW)	Similar Note03

Operation interface	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen	Same
Power Supply	AC power: 100 - 240 V~ 50/60 Hz; 6.5A Max Internal lithium battery: 14.8 V, 12,800 mAh; rechargeable; it can support the maximum power output of the product for at least 30 min when it is fully charged.	100-240V AC,50/60Hz 2.5A Max	100 - 240 VAC, 47/63Hz, 1.06- 0.45A	Similar Note04
Microprocess or Control	Yes	Yes	Yes	Same
Standard	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	Same

As seen in the comparison tables, the subject device uses similar 1470nm diode laser technology as that used by the predicates. The subject device has the same classification information, same indications and intended use, same design principle, same therapeutic laser technical features similar aiming beam (light) technical features and power supply. The minor differences only exist in the technical features of the aiming beam (light) and the power supply. Moreover, both the subject devices and the predicate devices meet the same standards, namely IEC60601-1, IEC60601-1-2, IEC60601-2-22 and IEC60825-1. The differences between the subject device and predicate devices do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

## **8. Discussion of Non-clinical Testing**

To verify the performance requirements of SurgiLight 1470 Diode Laser System (model:Halo) the following tests were performed. It shows that the testing results do support substantial equivalence.

IEC 60601-2-22:2019

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

IEC 60601-1-2:2014+A1:2020

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

IEC 60825-1: 2014

Safety of laser products -Part 1:Equipment classification and requirements

ANSI/AAMIES60601-1:2005/A2:2021

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance .

## **9. 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, "Content of Premarket Submissions for Device Software Function". The recommended Documentation Level for software of this device was considered as a "Basic Documentation Level " and the documentation was provided accordingly.

## **10. Brief discussion of clinical tests**

No human clinical data is need for SurgiLight 1470 Diode Laser System (model:Halo) .

## **11. Conclusion**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Micro-Energy Medical Technology Co., Ltd concludes that:

- The indications for use of SurgiLight 1470 Diode Laser System (model:Halo) are the same as those of the predicate devices.
- The technological characteristics are the same or similar to those of the predicate devices.
- Demonstrated by the safety and performance tests, SurgiLight 1470 Diode Laser System (model:Halo) is substantially equivalent to the predicate devices.