October 20, 2025

Sanhe LEFIS Electronics Co., Ltd.
Dandan Wang
Registration Manager
Bldg 11 #1-101, Phase 1,Zhongnan High tech·Yanjiao Science &
Technology Innovation Smart Valley Industrial Park 1
Langfang, Hebei 065201
China

Re: K252319
Trade/Device Name: Q-Switched Nd: YAG Laser machine (LFS-C13U)
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: July 25, 2025
Received: July 25, 2025

Dear Dandan Wang:

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: 2025.10.20 23:05:05 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252319

Device Name
Q-Switched Nd: YAG Laser machine (LFS-C13U)

Indications for Use *(Describe)*
The Q-Switched Nd: YAG Laser machine is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows:

1064nm:
-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.

532nm:
-Tattoo Removal
Light ink: red, Light ink: sky blue and green.
- Treatment of Benign Vascular Lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of Benign Pigmented Lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

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.

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510(k) Number: K252319

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Submission: 2025/7/25

2. Sponsor Identification

Sanhe LEFIS Electronics Co., Ltd.

Building 11 #1-101, Phase 1, Zhongnan High tech· Yanjiao Science and Technology Innovation Smart Valley Industrial Park 1, South Side of Liushan Street and West Side of Gushan West Road, Yanjiao High tech Zone, Sanhe City, 065201 Langfang City, Hebei Province, China

Contact Person: Dandan Wang
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3. Designated Submission Correspondent

Ms. Dandan Wang

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4. Identification of Proposed Device

Trade Name: Q-Switched Nd: YAG Laser machine

Model Name: LFS-C13U

Common Name: Surgical Laser Device

Regulatory Information

Classification Name: Laser Surgical Instrument for Use In General And Plastic Surgery And In Dermatology

Classification: II

Product Code: GEX

Regulation Number: 21CFR 878.4810

Review Panel: General & Plastic Surgery

5. Intended Use and Indications for Use

The Q-Switched Nd: YAG Laser machine is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows:

1064nm:

-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.

532nm:

-Tattoo Removal
Light ink: red, Light ink: sky blue and green.
- Treatment of Benign Vascular Lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of Benign Pigmented Lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

6. Environment of Use

Medical institutions, including hospitals, clinics, etc.

7. Product Description

The Q-Switched Nd: YAG Laser machine is a laser system which delivers light at a wavelength 1064nm or 532nm. The Q-Switched Nd: YAG Laser machine is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology. The device comprises a main unit, light guide arm and footswitch.

Table 1 Main Components introduction

Component name	Function
Main unit	Main Interface
Light guide arm	Articulated arm for holding of Treatment Probe
Footswitch.	Control pulse light output

Table 2 external dimensions

Overall weight	≤100kg
Volume (without light guide system)	1000mm×480mm×1050mm

Working Principle

The working principle of Q-Switched Nd: YAG Laser machine is that neodymium ions in neodymium doped yttrium aluminum garnet crystals are excited by the energy provided by the pump source and release photons. These photons are repeatedly reflected and stimulated to emit in the optical resonant cavity of the crystal, ultimately producing a specific wavelength (mainly 1064nm) and high energy density laser beam. It can also be converted from a 1064nm wavelength laser beam to a 532nm laser beam through frequency doubling technology; Then, it is effectively transmitted to the treatment site through the beam transmission device and plays a therapeutic role through the photothermal effect.

8.Materials

Components	**Material**	**Category**	**Contact Level**	**Contact Duration**
Treatment Head	Al Alloy	Surface device	Intact skin	Short-term (<24h)

The treatment hand piece used in the Machine has passed the Biocompatibility test. For details, please refer to "Biocompatibility Discussion".

9. Identification of Predicate Device(s)

510(k) Number: K193609
Product Name: Q-Switched Nd: YAG Laser machine
Manufacturer: Beijing Lead Beauty S&T Co., Ltd.

510(k) Number: K173038
Product Name: CuRAS Nd:YAG Laser
Manufacturer: Ilooda Co., Ltd

10. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI/AAMI ES60601-1:2005, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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 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 60825-1 2014 Safety of laser products - Part 1: Equipment classification, and requirements

The body-contacting components of this device are the treatment head. The biocompatibility evaluation for the Q Switched Nd: YAG Laser machine was conducted in accordance with the guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process"” as recommended by FDA.T he treatment head is considered skin and subcutaneous tissue contacting for a duration of less than 24 hours. The biocompatible testing included In Vitro Cytotoxicity, Skin Sensitization and Intracutaneous Reactivity was conducted in compliance with:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993- 10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation.

In summary, the results of the non-clinical tests indicate that the device complies with relevant international standards in terms of basic safety and essential performance, electromagnetic interference, laser safety, and biocompatibility. This demonstrates the safety and effectiveness of the device, providing a scientific basis for further clinical application and market access. Detailed test methods and results can be found in the test report.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Content of Premarket Submissions for Device Software Functions". The software for this device was considered as an "Enhanced" documentation level. Software validation demonstrated that the software functions as specified in the software requirement specifications.
- Bench performance testing to show that the device delivers set laser energy parameters within specifications.

Sterilization and Shelf-Life

The proposed device is not provided sterile and does not need to be sterilized. The handpiece and the body are cleaned with a soft cloth moistened with isopropyl alcohol or ethanol of 75% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

11. Technological characteristics and substantial equivalence:

Table 1 General Comparison

ITEM	**Proposed Device**	**Predicate Device1 K193609**	**Predicate Device 2 K173038**	**Remark**
Device Name	Q-Switched Nd: YAG Laser machine	Q-Switched Nd: YAG Laser machine	CuRAS Nd:YAG Laser	SE
Manufacturer	Sanhe LEFIS Electronics Co., Ltd.	Beijing Lead Beauty S&T Co., Ltd.	Ilooda Co., Ltd	SE
Product Code	GEX	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Class	Class II	Class II	Class II	SE
Intended Use	The Q-Switched Nd: YAG Laser machine is indicated for use in	The Q-Switched Nd: YAG Laser Therapy System is indicated	The CuRAS Nd:YAG laser	SE

	tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows: 1064nm: -Tattoo Removal Dark ink: blue and black. -Treatment of Benign Pigmented Lesions Nevus of ota. 532nm: -Tattoo Removal Light ink: red, Light ink: sky blue and green. - Treatment of Benign Vascular Lesions Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi. -Treatment of Benign Pigmented Lesions Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.	for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows: 1064nm: -Tattoo Removal Dark ink: blue and black. -Treatment of Benign Pigmented Lesions Nevus of ota. 532nm: -Tattoo Removal Light ink: red, Light ink: sky blue and green. - Treatment of Benign Vascular Lesions Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi. -Treatment of Benign Pigmented Lesions Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.	system in indicated for: the incision,excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 532nm Wavelength:-Tattoo removal:light ink(red,tan,purple,orange,skyblue,green -Removal of Epidermal Pigmented Lesions -Removal of Minor Vascular Lesions including but not limited to telangiectasias -Treatment of Lentigines -Treatment of Cafe-Au-Lait -Treatment of Seborrheic Keratoses -Treatment of Post Inflammatory	

			Hyper-Pigmentation -Treatment of Becker's Nevi, Freckles and Nevi Spilus 1064nm Wavelength: -Tattoo removal: dark ink(black, blue and brown)Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation.-Treatment of Common Nevi-Skin resurfacing procedures for the treatment of acne scars and wrinkle	

Table 2 Technological characteristics

ITEM	**Proposed Device**	**Predicate Device1K193609**	**Predicate Device 2 K173038**	**Remark**
Laser	ND:YAG	ND:YAG	ND:YAG	SE
Wavelength	1064nm 532nm	1064nm 532nm	1064nm 532nm	SE

ITEM	Proposed Device	Predicate Device1K193609	Predicate Device 2 K173038	Remark
Output Power (Maximum)	1064nm: 800mJ 532nm:250mJ	500mJ for 1064nm 260mJ for 532nm	Max 1.6J @1064 nm Max 0.4J @532 nm	Different Note 1
Spot Size	2-10mm	2-10mm	2mm-10mm	SE
Pulse Width	4ns-16ns	6ns±1ns	5-20ns	SE
Aiming Beam Wavelength	630 nm-670 nm	635nm	635nm	Different Note 2
Max.Aimig BeamPower Watts	≤ 1mW	0.1mW-5mW	5mW	Different Note 2
Laser Class	Class 4	Class 4	Class 4	SE
Laser output mode	Q-switched pulse	Q-switched pulse	Q-switched pulse	SE
Repetition rate	1-10Hz	1-10Hz	1-15Hz	SE
Beam delivery	articulated arm light guide	articulated arm light guide	Articulated arm	SE
Cooling System	internal distilled water circulating cooling	internal distilled water circulating cooling	/	SE
Power Input	110VAC, 60Hz; 230VAC, 50Hz	/	220-230VAC, 50-60 Hz	SE

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device1 K193609	Predicate DeviceK173038	Remark
Patient contact material	Aluminum alloy	Aluminum alloy	/	SE
Biocompatibility	Passed the test as per ISO 10993-5， ISO 10993-10andISO10993-23	Passed the test as per ISO 10993-5 and ISO 10993-10	/	SE
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

Note 1:

Different - Output Power (Maximum)
The proposed device has different Maximum pulse energy from the predicate device. Additionally, the reference devices K193609 and K173038 that we have listed have similar intended uses to the proposed device. The maximum pulse energy of the proposed device is greater than that of K193609, but the maximum pulse energy of the reference device K173038 encompasses the pulse energy of the proposed device. Therefore, we believe that a maximum pulse energy of 800mJ for 1064nm is a mature parameter that will not affect the safety and effectiveness of the equipment. The difference in output energy will not impact safety and effectiveness, as the ultimate safety and effectiveness regarding clinical indications will depend on the amount of energy output per unit area, which will produce thermal effects to the irradiated skin area of the patient to achieve the claimed indication for use. Moreover, the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test, and performance test, ensuring the safety of the product.

Note 2:

Different - Aiming beam wavelength and Power

The proposed device has different Aiming beam wavelength and Power from the predicate device. For the difference on Aiming beam wavelength and Power between the predicate and proposed device(s), we can see that the proposed device has similar Aiming beam wavelength and Power with predicate device (K193609). They are only with minor difference. And we think this minor difference will not affect the effectiveness and safety.

And the purpose of aiming beam is only for aiming. And at the same power, the difference in the Wavelength and Power of the aiming beam will only cause differences in visual color and brightness, and will not affect the effectiveness and safety.

Conclusion:

Q-Switched Nd: YAG Laser machine is substantial equivalent to the predicate device.

12. Clinical Test Conclusion

No clinical study is included in this submission.

13. Substantially Equivalent(SE) Conclusion

Q-Switched Nd: YAG Laser machine the same intended use, similar indications for use, the same technological characteristics, the same energy used, and the same operating principles as its predicates.The non-clinical data and performance testing reports in this submission demonstrate that Q-Switched Nd: YAG Laser machine meets the expected performance requirements. Any difference between the subject and predicate device do not raise new issues of safety or effectiveness. Based on above analysis, Q-Switched Nd: YAG Laser machine is substantial equivalent to the cited predicate device.