May 11, 2026

Speclipse, Inc.
Heajung Kim
Sr. RA Manager
Contact Address

Re: K261214
Trade/Device Name: PICO SHINING (PICO-K; PICOFY)
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 15, 2016
Received: April 15, 2026

Dear Heajung 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 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.05.11 16:47:53 -04'00'

for 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.

510(k) Number *(if known)*
K261214

Device Name
PICO SHINING (Model : PICO-K, PICOFY)

Indications for Use *(Describe)*
The PICO SHINING is intended for use in the following indications at the specified wavelength:

1064 nm wavelength
-Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple
-Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV
-Treatment of acne scars in Fitzpatrick Skin Types II-V
-Treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV

532 nm wavelength
-Tattoo removal in Skin Types I - III
-Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV

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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510(k) Summary

510(k) Summary - K261214

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

April. 06, 2026

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: SPECLIPSE, Inc.
- Address: #501, #502, #503, #504, #505, 232, Sandan-ro, Danwon-gu, Ansan-si, Gyeonggi-do, 15433, Republic of Korea
- Contact Name: Hea Jung Kim
- Telephone No.: +82-31-698-2269
- Email Address: hjkim@speclipse.com
- Registration No.: 3013697074

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

510(k) Number	K261214
Trade/Device/Model Name	PICO SHINING (Model: PICO-K, PICOFY)
Product Name	Nd:YAG Surgical Laser Equipment
Common Name	Laser Surgical Instrument
Regulation Name	Powered Laser Surgical Instrument
Regulation Number	21 CFR 878.4810
Classification Product Code	GEX
Device Class	II
510(k) Review Panel	General & Plastic Surgery

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

510(k) Number	K253342
Trade/Device/Model Name	PICO-K
Common Name	Laser Surgical Instrument
Device Classification Name	Powered laser surgical instrument
Regulation Number	21 CFR § 878.4810
Classification Product Code	GEX
Device Class	Class II
510(k) Review Panel	General & Plastic Surgery

The predicate device has not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

The PICO SHINING consists of a power supply, laser resonator, touch LCD monitor, articulated arm, handpieces, foot switch, and laser protective eyewear. The system includes several safety features, including use of key switch, an interlock, emergency stop button, and need to press a footswitch in order to activate the laser. The main body transmits the laser energy through the articulating arm to the handpiece which is positioned above or in contact with the treatment area. Four different handpieces can be attached to the articulated arm, the Zoom handpiece, Collimated handpiece, and Array MLA 110 and Peak MLA 60 handpiece. Each handpiece is interchangeable and integrates and aiming beam that shows the treatment area.

The Nd:YAG laser surgical system employs a solid-state laser with a medium of Nd:YAG at 1064 nm and KTP at 532 nm. The energy from the 1064 nm wavelengths emitted by the laser is directed at the cells or tissues of the skin, raising the temperature of the targeted tissue according to the Selective Photothermolysis Theory. This selective heating of the tissue results in the cutting, destruction, or removal of the tissue through the heat energy produced by the laser. The system employs a patented resonator design with optics aligned under controlled thermal lensing conditions. At high repetition rates (8–10 Hz), thermal lensing of the Nd:YAG rod can degrade beam quality in conventional systems. In the system, the lamp frequency is fixed at 8–10 Hz, optical alignment is optimized under these conditions, and laser emission is generated only at divisor frequencies (1, 2, 3, 4, 5, 8, 9, 10 Hz). As a result, stable beam quality and energy output are maintained even during prolonged use.

6. Indications for Use [21 CFR 807.92(a)(5)]

The PICO SHINING is intended for use in the following indications at the specified wavelength.

- 1064 nm wavelength

  -Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple

  -Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV

  -Treatment of acne scars in Fitzpatrick Skin Types II-V

  -Treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV

- 532 nm wavelength

  -Tattoo removal in Skin Types I - III

  -Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV

7. Substantial Equivalence [21 CFR 807.92(a)(6)]

All devices have the same intended use, laser use in dermatological surgical and aesthetic applications. The subject device has equivalent indications to the predicate in that it shares indications with the predicate device.

The technological characteristics of the subject device are equivalent to the predicate device. Both devices share the same laser medium (Nd:YAG), primary wavelengths (1064 and 532 nm), and pulse widths in the picosecond timescale. The subject device maintains the same treatment modes and laser resonator technology as the predicate device.

The primary difference lies in the handpiece configuration. The MLA handpiece, previously cleared in the predicate device, has been renamed to Array MLA 110 in the subject device with no changes to its functional specifications. Additionally, the Peak MLA 60 handpiece has been introduced. The distinguishing feature of the Peak MLA 60 is the implementation of specific fluence limits for each individual spot, which are strictly controlled via software to prevent the repetition rate (Hz) from exceeding pre-defined safety thresholds. Performance bench testing has confirmed that these software-controlled fluence limits, along with the resulting wavelength, pulse energy and spot size, remain strictly within the maximum cleared ranges of the predicate's MLA technology.

All other laser parameters are identical to or a subset of the predicate device. Therefore, the renaming of the handpiece and the addition of the Peak MLA 60 with defined fluence limits do not raise any new questions of safety or effectiveness.

[Comparison of Proposed Device to Predicate Device]

	Subject Device	Predicate Device	Note
K Number	K261214	K253342	-
Manufacturer	SPECLIPSE, Inc.	SPECLIPSE, Inc.	Identical
Device Name	PICO SHINING	PICO-K	Updated to include the new model, "PICOFY."
Model	PICO-K, PICOFY	PICO-K	Added a new model variant, PICOFY.
Product Code	GEX	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
510(k) Review Panel	General & Plastic Surgery	General & Plastic Surgery	Identical
Indications for Use	1064 nm wavelength -Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple -Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV -Treatment of acne scars in Fitzpatrick Skin Types II-V -Treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV 532 nm wavelength -Tattoo removal in Skin Types I - III -Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV	1064 nm wavelength -Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple -Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV -Treatment of acne scars in Fitzpatrick Skin Types II-V -Treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV 532 nm wavelength -Tattoo removal in Skin Types I - III -Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV	Identical

	Subject Device	Predicate Device	Note
Laser Source	Nd:YAG	Nd:YAG	Identical
Wavelength	532/1064 nm	532/1064 nm	Identical
Pulse Energy	**1064nm:** Up to 605 mJ **532nm:** Up to 254 mJ	**1064nm:** Up to 605 mJ **532nm:** Up to 254 mJ	Identical
Pulse Width	**1064nm:** 300ps **532nm:** 300ps	**1064nm:** 300ps **532nm:** 300ps	Identical
Max. Repetition Rate (Hz)	**1064nm:** 10 Hz **532nm:** 10 Hz	**1064nm:** 10 Hz **532nm:** 10 Hz	Identical
Spot Size	**Zoom**: 2-10 mm **Collimation**: 8 mm **Array MLA 110:** 4-12 mm **Peak MLA 60**: 4-12 mm	**Zoom**: 2-10 mm **Collimation**: 8 mm **MLA**: 4-12 mm	Identical
Power Input	220-230VAC 50/60Hz, 9A	220-230VAC 50/60Hz, 9A	Identical

8. Non-Clinical Test Summary

The PICO SHINING complies with voluntary standards for electrical safety, electromagnetic compatibility.

1) Electrical Safety, Electromagnetic Compatibility and Performance:

PICO SHINING complies with the electrical safety and electromagnetic compatibility (EMC) requirements established by the applicable standards. Testing was conducted on the representative model, PICO-K, and the results cover all models within the series.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60601-1	IEC	Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance	3.2	2020
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	4.1	2020
60601-2-22	IEC	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	4.0	2019
60825-1	IEC	Safety of laser products – Part 1: Equipment classification and requirements	3.0	2014

3) Software Validation

The 'PICO-K and PICOFY' contains enhanced level documentation. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices, on June 14, 2023

4) Bench Testing

Bench testing of the laser output energy, wavelength, repetition rate, spot size, pulse width, and beam output was conducted to verify the device's performance and to demonstrate that it achieves its claimed performance. These results support the demonstration of substantial equivalence to the predicate device.

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the subject device and the predicate device, K253342 that would adversely affect the use of the product. It is substantially equivalent to the device in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In conclusion, the subject and predicate device have identical intended use. The sole technical difference is the addition of a handpiece, which operates within the cleared performance specifications. Other administrative changes are reflected in the labeling and our Quality Management System (QMS) documentation. Furthermore, a comprehensive risk impact assessment has been completed for all modifications.