December 24, 2025

Speclipse., Inc.
Myung Seo Park
Quality Management Representative
#501, #502, #503, #504, #505, 232, Sandan-Ro, Danwon-Gu,
Ansan-Si
Gyeonggi-Do, 15433
Republic Of Korea

Re: K253342
Trade/Device Name: Pico-k
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: September 30, 2025
Received: September 30, 2025

Dear Myung Seo Park:

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: 2025.12.24 00:22:08 -05'00'

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253342

Please provide the device trade name(s).

PICO-K

Please provide your Indications for Use below.

The PICO-K 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

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

[As Required by 21 CFR 807.92]

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

Aug. 30, 2025

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: Myung Seo Park
- Telephone No.: +82-31-698-2269
- Email Address: mspark@speclipse.com
- Registration No.: TBD

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

510(k) Number	K253342
Trade/Device/Model Name	PICO-K
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;

- Predicate device #1

510(k) Number	K202172
Trade/Device/Model Name	StarWalker
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

- Predicate device #2

510(k) Number	K201773
Trade/Device/Model Name	PICOHI
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

These predicate devices have not been subject to a design-related recall.

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

The system 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. Three different handpieces can be attached to the articulated arm, the Zoom handpiece, Collimated handpiece, and MLA handpiece. Each handpiece 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.

PICO-K 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 PICO-K, 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).

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

The PICO-K 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 predicate #1, in that it is a subset of the predicate device (it does not have the indications related to use in PTP or multi-peak mode or use with Dye handpieces). Predicate #2 has equivalent indications, although they do not match verbatim. In sum, the subject device has the same intended use as either of the predicates.

The technological characteristics between the subject and the predicate devices are similar. All devices have two primary wavelengths, 1064 and 532 nm and pulse widths in the picosecond timescale. The subject device has only one treatment mode, whereas K202172 also has Q-switched PTP, multi-peak, and long pulse modes. As the subject device is a subset of the predicates, it does not raise any questions regarding safety or effectiveness. Similarly, the handpieces available in the subject device match those provided in K201773 and include Zoom, Collimation, and MLA. This predicate additionally includes multiple types of MLA handpieces (VMLA and ZMLA) as well as a DOE handpiece. As the subject device is a subset of the predicates, it does not raise any questions regarding safety or effectiveness. The laser parameters of the subject device, including wavelength, pulse energy, pulse width, repetition rate, and spot size are within the ranges cleared for either or both predicates. Differences in fluence are within range of both predicate devices.

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
K Number	K253342	K202172	K201773	-
Manufacturer	SPECLIPSE, Inc.	Fotona d.o.o.	Hironic Co., Ltd.	-
Device Name	PICO-K	StarWalker	PICOHI	-
Product Code	GEX	GEX	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
510(k) Review Panel	General & Plastic Surgery	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 in Q-switched mode: -Removal of dark (black, blue, brown) tattoo ink -Treatment of nevus of ota -Treatment of common nevi -Removal and lightening of unwanted hair -Skin resurfacing procedures for the treatment of acne scars and wrinkles -Treatment of melasma -General dermatology indications: Incision, excision, ablation and vaporization of soft tissue 1064 nm wavelength in long pulse mode: -Removal of unwanted hair, for stable long term or permanent hair reduction and for	The PICOHI is indicated for the following at the specified wavelength: • 532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. • 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. • Treatment of benign pigmented lesions for Fitzpatrick skin types I-IV.	Identical

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
		treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin -Photocoagulation and hemostasis of benign pigmented and benign vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins -Coagulation and hemostasis of soft tissue -Treatment of wrinkles -Treatment of mild to moderate inflammatory acne vulgaris 532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces): -Red, tan, purple and orange tattoo ink removal -Sky blue (light) tattoo ink removal -Green tattoo tattoo ink removal -Treatment of benign pigmented lesions including, but not		

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
		limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, senile lentigines, Becker's nevi, freckles, common nevi, nevus spilus -Treatment of benign vascular lesion including, but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi -Seborrheic Keratosis -Treatment of post-inflammatory hyperpigmentation -Skin resurfacing procedures for the treatment of acne scars and wrinkles -Removal of epidermal pigmented lesions 532 nm wavelength in long pulse mode: -Incision, ablation vaporization, coagulation and hemostasis of vascular lesions and soft tissue in various surgical areas. All soft tissue is included, such as skin, cutaneous tissue, subcutaneoous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and		

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
		nodes, organs and glands. -The treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size) of the benign vascular lesions (Angiomas, Hemangiomas, Telangiectasia) 1064 nm wavelength in PICO mode: -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 in PICO mode: -Tattoo removal in Skin Types I - III -Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV		
Laser Source	Nd:YAG	Nd:YAG	Nd:YAG	Identical
Wavelength	532/1064 nm	532/1064 nm	532/1064 nm	Identical

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
Pulse Energy	**1064nm:** Up to 605 mJ **532nm:** Up to 254 mJ	**1064nm:** PICO Nd:YAG: Up to 800 mJ Q-switched: Up to 1600 mJ Long pulsed Up to 15000 mJ **532nm:** PICO KTP: Up to 300 mJ Q-switched: Up to 600 mJ Long pulsed: Up to 2000 mJ	Not disclosed in public documentation	Pulse Energy is within range of predicate #1
Pulse Width	**1064nm:** 300ps **532nm:** 300ps	**1064nm:** PICO Nd:YAG: 300 - 400 ps Q-switched: 5 -20 ns Long pulsed: 0.6 - 50 ms **532nm:** PICO KTP: 300 - 400 ps Q-switched: 5 – 20 ns Long pulsed: 15 - 50ms	275-300 ps	Pulse Width is within range of predicates #1 and #2
Max. Repetition Rate (Hz)	**1064nm:** 10 Hz **532nm:** 10 Hz	**1064nm:** PICO Nd:YAG: 0.5 - 10 Hz Q-switched: 0.5 - 15 Hz **532nm:** PICO KTP: 0.5 - 8 Hz Q-switched: 0.5 - 10 Hz Long pulsed: 0.5 - 1 Hz	10Hz	Repetition Rate is within range of predicate #2

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
Spot Size	**Zoom**: 2-10 mm **Collimation**: 8 mm **MLA**: 4-12 mm	- Not disclosed in public documentation	**Zoom:** 1064nm: 10 mm 532 nm: 1.5-7.5 mm **Collimated**: 10 mm **MLA**: VMLA: 13 mm ZMLA: 12 mm **DOE**: 10 mm	Spot Size is within range of predicate #2
Power Input	220-230VAC 50/60Hz, 9A	- Not disclosed in public documentation	220-240VAC, 50/60Hz, 20A	Power Input is within range of predicate #2

8. Non-Clinical Test Summary

The 'PICO-K' complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The 'PICO-K' complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

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

Standards No.	Standards Organization	Standard Title	Version	Publication Year
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

2) Biocompatibility Testing

The 'PICO-K complies with the bio-compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	3.0	2009
10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	4.0	2021
10993-23	ISO	Biological evaluation of medical devices - Part 23: Tests for irritation	1.0	2021

3) Software Validation

The 'PICO-K' 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:

- Content of Premarket Submissions for Device Software Functions, 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 proposed device and the predicate device, K202172 and K201773 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

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

In conclusion, the subject and predicate devices have identical intended use and equivalent indications. The differences in technological characteristics do not raise different questions and bench testing has demonstrated substantial equivalence.