



January 30, 2026

Boston Aesthetics INC
Cao Hongmei
General manager
1521 Concord Pike Suite 201
Wilmington, Delaware 19803

Re: K251981

Trade/Device Name: Boston PICO (Boston PICO)

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: June 27, 2025

Received: December 31, 2025

Dear Cao Hongmei:

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: 2026.01.30
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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)

K251981

Device Name

Boston PICO (Boston PICO)

Indications for Use (Describe)

The Boston PICO is indicated for surgical and cosmetic use in dermatology department, general surgery department and plastic surgery department, details are as follows:

1064 nm wavelength:

– Remove tattoos of all skin types (Fitzpatrick skin type I-VI) in the following colors: black, brown, green, blue and purple.

– Treat benign pigmented skin lesions of Fitzpatrick I-IV types.

532 nm wavelength:

– Remove tattoos of Fitzpatrick skin type I-III in the following colors: red, yellow and orange.

– Treat benign pigmented skin lesions of Fitzpatrick I-IV types.

Microbeam handpieces (1064nm and 532nm) are used for the treatment of wrinkles for 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

#K251981

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of 21 CFR §807.92.

1. Administrative Information

Preparation Date

2026-01-29

Submission Correspondent

Name: Boston Aesthetics INC

Address: 1521 Concord Pike Suite 201 Wilmington DE 19803

Tel: +001 949-792-8168

E-mail: bsnaesthetics@gmail.com

Contact: Ms. Hongmei Cao

2. Device Information

Device Name:	Boston PICO
Model:	Boston PICO
Manufacturer:	Boston Aesthetics INC
Regulation Description:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Medical Specialty:	General & Plastic Surgery
Regulation Number:	878.4810
Product Code:	GEX
Device Class:	2
Type of 510(k) Submission:	Traditional

3. Predicate Device

Device name:	PicoWay Laser System
Manufacturer:	Candela Corporation
Regulation Description:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Medical Specialty:	General & Plastic Surgery
Regulation Number:	878.4810
Product code:	GEX
Device Class:	2
510(K) Number:	K191685

4. Reference Device

Device name:	PICOCARE MAJESTY
Manufacturer:	WonTech Co., Ltd.
Regulation Description:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Medical Specialty:	General & Plastic Surgery
Regulation Number:	878.4810
Product code:	GEX
Device Class:	2
510(K) Number:	K241144

5. Intended Use/Indication for Use

The Boston PICO is indicated for surgical and cosmetic use in dermatology department, general surgery department and plastic surgery department, details are as follows:

1064 nm wavelength:

- Remove tattoos of all skin types (Fitzpatrick skin type I-VI) in the following colors: black, brown, green, blue and purple.
- Treat benign pigmented skin lesions of Fitzpatrick I-IV types.

532 nm wavelength:

- Remove tattoos of Fitzpatrick skin type I-III in the following colors: red, yellow and orange.
- Treat benign pigmented skin lesions of Fitzpatrick I-IV types.

Microbeam handpieces (1064nm and 532nm) are used for the treatment of wrinkles for skin types I-IV.

6. Device Description

The Boston PICO is a multi-wavelength, pulsed laser system, and a solid-state laser capable of delivering energy at wavelengths of 1064nm, 532nm at extremely short duration in 250ps(\pm 20%). The combination of wavelength, pulse duration and energy fluence are disrupting the tattoo dye or pigment particles under the skin without harming the surrounding tissue. The fragmented dye or pigment particles eventually surface and fade as the epidermal layer of the skin is renewed. The 1064 nm wavelength can be frequency-doubled to 532nm as desired. The outputs of the two lasers are designed to be co-linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532 nm or 1064 nm wavelengths. All these energies are delivered through an articulated arm and corresponding handpiece.

7. Comparison with predicate device

Items	Subject Device	Predicate device (K191685)	Reference Device (K241144)	Comparison
Name	Boston PICO	PicoWay Laser System	PICOCARE MAJESTY	/
Model	Boston PICO	/	/	/
Type of use	Prescription Use	Prescription Use	Prescription Use	Same
Anatomical Site	Skin and subcutaneous tissue	Skin and subcutaneous tissue	Skin and subcutaneous tissue	Same
Handpiece	Zoom handpiece (1064nm, 532nm) 1064 handpiece (1064nm) 1064x handpiece (1064nm) 532 handpiece (532nm) 532x handpiece (532nm)	Zoom handpiece(532nm, 1064 nm) Resolve handpiece(1064nm) Resolve High energy handpiece (532nm)	Zoom(1064nm, 532nm) DOE (1064nm, 532nm)	Comparable
Wavelength	1064nm; 532nm	1064nm; 532nm	1064nm; 532nm	Same
Pulse Duration	250ps	240-500ps	275~300ps	Comparable
Max pulse energy	Zoom(1064): 500mJ Zoom(532): 250mJ 1064, 1064x: 400 mJ 532, 532x: 200mJ	Zoom(1064): 400mJ Zoom(532): 200mJ Resolve 1064: 290mJ Resolve High Energy(532nm): 150mJ	Zoom(1064): 500mJ Zoom(532): 250mJ DOE (1064nm): 450mJ DOE (532nm): 200mJ	Comparable
Fluence	Zoom(1064nm): 0.12~15.7J/cm ² Zoom(532nm): 0.06~7.6 J/cm ² 1064, 1064x: 0.1~4.0 mJ/MTZ 532, 532x: 0.1~ 2.0 mJ/MTZ	Zoom(1064): 0.20-12.5J/cm ² Zoom(532): 0.16-6.25J/cm ² Resolve 1064: 0.5-2.9 mJ/ubeam Resolve High Energy(532nm): 0.2-1.6mJ/ubeam	Zoom(1064): 0.2 ~ 10.0 J/cm ² Zoom(532): 0.1 ~ 2.5 J/cm ² DOE (1064nm): 0.4 ~ 5.5 mJ/μbeam DOE (532nm): 0.25 ~ 2.5 mJ/μbeam	Comparable
Max pulse power	Zoom(1064): 2.0 GW Zoom(532): 1.0 GW 1064, 1064x: 1.6 GW 532, 532x: 0.8 GW	Zoom(1064): 0.9 GW (400 mJ) Zoom(532): 0.5 GW (200 mJ) Resolve 1064: 0.64 GW Resolve High Energy(532nm): 0.33 GW	Zoom(1064): 2.0 GW Zoom(532): 1.3 GW DOE (1064nm): 1.8 GW DOE (532nm): 1.05 GW	Comparable
Repetition Rate	Single, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz	Single, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz	Single, 1 ~ 10 Hz	Same

Items	Subject Device	Predicate device (K191685)	Reference Device (K173700)	Comparison
Spot Size	Zoom: 2 mm - 10 mm 1064x: 10mm×10mm 1064: 6mm×6mm 532x: 10mm×10mm 532: 6mm×6mm	Zoom: 2 mm - 10 mm Resolve 1064: 6mm×6mm Resolve High Energy(532nm): 6mm×6mm	Zoom: 2 mm - 10 mm DOE (1064nm): 9mm×9mm DOE (532nm): 9mm×9mm	Comparable
Aiming Beam	Wavelength:620nm - 670nm, unadjustable Optical power: < 5mW	Wavelength: 650nm. ±20%, unadjustable Optical power: < 3.5mW	Not Publicly Available	Comparable
System dimension	1000x400x1200(mm) (L×W×H) Not including light guide articulated arm	1090x408x763(mm) Height does not include articulated arm	Not Publicly Available	Comparable
Weight	About 100kg	About 122kg	About 99kg	Comparable
Rated voltage and power	110-220 VAC; 10A; 50/60 Hz Input power rate: 2500VA	200-240 VAC; 50/60 Hz; 30A 4600 VA, single phase	200-240 VAC, 50/60 Hz, 4.0kVA	Comparable

The subject device and the predicate device have the same intended use. Although the subject device and the predicate device have several different technological characteristics as noted in the table above, the differences do not raise different questions of safety and effectiveness. Therefore, we consider that the subject device is as safe and effective as the predicate device

8. Non-Clinical Performance Testing

8.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has passed safety testing in according to following standards.

- 1) IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 2) 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
- 3) IEC 60825-1: 2014 Safety of laser products - Part 1: Equipment classification and requirements
- 4) 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
- 5) IEC TS 60601-4-2: 2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

8.2. Biocompatibility Test

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance “Use of International Standard ISO 10993, Biological Evaluation of Medical Device Part 1: Evaluation and Testing.” The testing includes:

- 1) Cytotoxicity per ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity.
- 2) Sensitization per ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- 3) Irritation per ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- 4) Systemic toxicity per ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

The user- contacting materials were shown to be non-cytotoxic, non-irritating and non-sensitizing.

8.3. Performance test

The proposed device meet the specification and performance characteristics as identified in design control procedures and are substantially equivalent to the predicate device. The performance tests of the subject device which were conducted included but not limited to laser wavelength, pulse width, terminal maximum single pulse energy, maximum pulse power, repeat pulse frequency, treatment spot diameter, treatment energy and treatment energy intensity. All the test results meet the acceptance criteria.

8.4 Software verification and validation

Software documentation of the subject device was provided in accordance with the FDA guidance Document- “*Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff*”, which was issued in 06/14/2023 to support a device’s Basic

Documentation Level.

8.5 In vitro testing

Ex vivo testing of the Boston PICO with different handpieces was conducted to evaluate the mechanism by which the device interacts with tissue, as well as its safety and effectiveness, without involving a complete living system.

9. Animal testing

Animal studies allow simulation of in vivo treatment conditions to verify the mechanism of action of the Boston PICO device on biological tissues, and to evaluate its safety and effectiveness under actual use conditions.

10. Clinical data

No clinical study is included in this submission.

The Substantial equivalence does not depend on the clinical test data.

11. Conclusion

The subject device and the predicate device have the same intended use and any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness. The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device (K191685) and supports a determination of substantial equivalence.