May 21, 2026

Boston Aesthetics, Inc.
Hongmei Cao
General Manager
1521 Concord Pike
Suite 201
Wilmington, Delaware 19803

Re: K253245
Trade/Device Name: Boston 2910 (Boston 2910)
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 22, 2026
Received: April 22, 2026

Dear Hongmei Cao:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.05.21 18:01:45 -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)*
K253245

Device Name
Boston 2910 (Boston 2910)

Indications for Use *(Describe)*
The Boston 2910 Laser System with its accessories is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytids, furrows, fine lines, textural irregularities, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), benign pigmented lesions, and vascular dyschromia.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K253245

1. Administrative Information

Submission Date

2025-09-29

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. Chunyan Zhang

2. Device Information

Device Name:	Boston 2910
Model:	Boston 2910
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 Devices

Device name:	UltraClear Fractional Laser System
Manufacturer:	Acclaro 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:	K233803

Device name:	JOULE System
Manufacturer:	Sciton, 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
510(K) Number:	K180508

4. Indications for Use

The Boston 2910 Laser System with its accessories is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytids, furrows, fine lines, textural irregularities, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), benign pigmented lesions, and vascular dyschromia.

5. Device Description

The Boston 2910 Laser System consists of a host (including the laser source, power supply, control system, and water-cooling system) , a laser transmission fiber, a footswitch and handpieces. The host incorporates software-based controls that regulate the power supply and drive the laser source to emit laser energy. The energy is directed to the treatment site through focusing optical components. The laser beam is delivered via an optical fiber to the treatment handpiece, where it is applied to the target tissue for ablation, thereby achieving the intended therapeutic effect. A footswitch is used to activate or deactivate the laser output, while the water-cooling system provides thermal management for the laser source to ensure stable and continuous operation.

6. Substantially Equivalent Comparison

Comparison of the Indications for Use:

Indications for use statement of the subject and predicate devices are comparable.

Comparison of Technology:

Items	Subject Device	Predicate device (K233803)	Predicate device (K180508)	Comparison
Energy Source	Er:YAG	Er:YAG	Er:YAG	Same
Wavelength	2910 nm	2910 nm	2940 nm	Same
Repetition Rate	Up to 3Hz	Up to 3 Hz	Up to 3 Hz	Comparable
Pulse Duration	0.1 ms~3.0 ms	0.1ms ~ 3.0ms	0.5 ms ~ 1.5 ms	Comparable

Items	Subject Device	Predicate device (K233803)	Predicate device (K180508)	Comparison
Energy/pulse/ µbeam	160 HP: Ring mode: 0.6~ 3.0mJ Dot mode: 3.6 ~ 30.0mJ Dot Ring mode: 0.6~ 3.0mJ; 3.6~ 30.0mJ 2mm HP: 5.6~ 24.0 mJ 3mm HP: 7.1 ~24.0 mJ	Clear mode: 0.6-1.5 mJ Silk Mode: 1.5-3.0 mJ Ultra Mode: 3.6-30.0 mJ UltraClear mode: 0.6-1.5, 3.6-30.0 mJ	Up to 70 mJ/microbeam Up to 25 mJ/microbeam for epidermal nevi, telangiectasia, spider veins, actinic chelitis, keloids, verrucae, skin tags, anal tags, keratosis, scar revision (including acne scars)	Comparable
Fluence per µbeam	160 HP: 15.9 - 132.2 J/cm^2 2mm HP: 0.18~0.76 J/cm^2 3mm HP: 0.10~0.34 J/cm^2	15.9 - 132.2 J/cm^2	~3.0 J/cm^2	Comparable
Energy power	160 HP: 10W 2mmHP, 3mm HP: 8.5W	10W	30W	Comparable
Spot size	160 HP: 2mm, 3mm, 4mm, 5mm, 7.5mm, 10mm, 12.5mm, 15mm 2mm HP: 2.8mm × 2.8mm ~ 16mm × 16mm 3mm HP: 4.2mm × 4.2mm ~ 30mm × 30mm	2×2mm ~ 15×15mm	1.3x1.3mm ~ 20x20mm	Same
µbeam dia	160 HP: 0.17mm 2mm HP: 2mm 3mm HP: 3mm	0.17 mm	2mm and 4mm	Comparable
Dimension(mm)	825 ×400×1850 (L×W×H, including fiber arm)	Not Publicly Available	356 ×533 ×1041	Comparable
Weight	About 95 kg	Not Publicly Available	About 91 kg	Comparable
Rated voltage and power	110-240 VAC, 20 A, 50/60 Hz	100-240 VAC, 8.4A, 50/60 Hz	200-240 VAC, 25A, 50/60 Hz	Comparable

The Boston 2910 is substantially equivalent in design, function, operating principles, and intended use to the UltraClear Fractional Laser System(K233803) and Joule System (K180508) predicate devices, based on the information presented. The devices share the simlar design and technical features. Any minor design differences do not raise different questions of safety or effectiveness.

7. Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance;
- IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility;
- IEC 60601-2-22:2012, 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;
- Biocompatibility evaluation per ISO 10993 and FDA guidance;
- Software Validation & Verification Test;
- Bench Testing to verify the performance.

8. Clinical data

Clinical study was not needed to support substantial equivalence.

9. Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.