January 21, 2026

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

Re: K252369
Trade/Device Name: Boston Pico755
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: December 22, 2025
Received: December 22, 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: 2026.01.21 15:41:28 -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

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)*
K253269

Device Name
BSOTON PICO755

Indications for Use *(Describe)*
The Boston Pico755 is indicated for the removal of tattoos and benign pigmented lesions, including but not limited to Ota nevus, Hori spots (Hori nevus), and melasma. The Boston Pico755 with the 2 mm and 6 mm handpieces and the handpieces with Focus Array are indicated for the treatment of acne scars and wrinkles in 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

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

The assigned 510(k) Number: K252369

1. Administrative Information

Date of Preparation

2026-01-16

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 PICO755
Model:	Boston PICO755
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
Classification Name	Powered Laser Surgical Instrument

3. Predicate Device

Device name:	PicoSure Workstation
Manufacturer:	Cynosure LLC
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
Classification Name	Powered Laser Surgical Instrument

510(K) Number:	K210226

4. Intended Use

The Boston Pico755 is indicated for the removal of tattoos and benign pigmented lesions, including but not limited to Ota nevus, Hori spots (Hori nevus), and melasma. The Boston Pico755 with the 2 mm and 6 mm handpieces and the handpieces with Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV.

5. Device Description

The Boston Pico755 is a medical solid-state laser equipment which is indicated for the removal of tattoos and benign pigmented lesions, including but not limited to: Ota nevus, Hori spots (Hori nevus) and melasma. It has handpieces for the treatment of acne scars and wrinkles in skin types I-IV. The device is intended to be used in professional healthcare facilities by trained physicians only.

The subject device Boston Pico755 consists of main unit (including power module, laser module, control system and cooling system), a light guide articulated arm, a footswitch, a handpiece and protective Glasses. It is connected to supply mains directly through undetachable power cord and plug. There are 8 types of replaceable handpieces - Zoom S, Zoom X, M, M6, M8, M10, 755x, 755s, and operators can choose the appropriate handpiece according to treatment needs.

When the system automatically detects the model of the installed handpiece, it will display the corresponding treatment interface specific to that handpiece. Users can view or adjust relevant parameters such as wavelength, fluence, energy, spot size, and repetition rate directly from the interface. After turning on the device, set the Wavelength, Fluence, Frequency, Spot Size, etc. to be used then press the Footswitch in the READY state, the laser will be energized and transferred through the Articulated Arm and handpiece. The cooling system controls the heating caused by the laser output.

6. Comparison with predicate device

Items	Subject Device	Predicate Device (K210226)	Comparison
Name	Boston PICO755	PicoSure Workstation	/
Intended use/ Indications for use	The Boston Pico755 is indicated for the removal of tattoos and benign pigmented lesions, including but not limited to: Ota nevus, Hori spots (Hori nevus) and melasma. The Boston Pico755 with the 2mm and 6mm handpieces and the handpieces with Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV.	755nm: The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota. Hori macules (nevus of Hori), and Melasma. The PicoSure Workstation with the 2mm and 6mm handpieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV. 532nm: The PicoSure 532nm delivery system is indicated for tattoo removal and benign pigmented lesions removal in Skin Types I-III. 1064nm: The PicoSure 1064nm delivery	Similar

Items	Subject Device	Predicate Device (K210226)	Comparison
		system is indicated for tattoo and benign pigmented lesions removal.	
Wavelength	755nm	755nm	Same
Pulse Duration	450ps (±20%)	500 - 900ps	Comparable
Output mode	Single/ Repeat pulse	Single/ Repeat pulse	Same
Repeat pulse frequency	Single pulse, 1 Hz, 2.5 Hz, 5 Hz, 10 Hz	Single Shot, 1 Hz, 2.5 Hz, 5 Hz, 10 Hz	Same
Max pulse energy	Zoom S: 300mJ, 200 mJ @ 2mm Zoom X: 300mJ M; M6; M8; M10: 300mJ 755x: 232mJ 755s: 148mJ	Max 300mJ	Comparable
Max fluence/pulse energy	ZoomS: 6.37J/cm^2 ZoomX: 1.06 J/cm^2 M: 2.31 mJ/μbeam M6: 2.31 mJ/μbeam M8: 1.29 mJ/μbeam M10: 0.83 mJ/μbeam 755X: 2.32 mJ/μbeam 755S: 2.31 mJ/μbeam	6.37J/cm^2 (max. among all handpieces)	Comparable for all handpieces
Treatment spot diameter	Zoom S: 2-5 mm Zoom X: 6-10 mm M: 6-10mm, stepping 1mm M6: 6mm M8: 8mm M10: 10mm 755x: 10mm × 10mm 755s: 6mm × 6mm	Zoom 2-6mm; Fixed 5, 6, 8, 10 mm	Comparable
Patient Contacting Material	Aluminum Alloy	316 Stainless Steel	Comparable
Device dimension	942mm × 380mm × 1025mm (L×W×H, not including light guide articulated arm)	109 cm x 56cm x 107cm Note: Height with arm extended 158cm	Comparable
Device Weight	About 115kg	375 lb (171 kg)	Comparable
Electrical parameters	110-220VAC ±10%;10A, 50/60 Hz Input power rate: 2400 VA	200-240 V~, 4.5 kVA, 50/60 Hz, Single Phase	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.

7. Non-Clinical Performance Testing

7.1. 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

7.2. 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: 2017 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.

7.3. Performance test

Bench Testing was performed to verify the performance of the device and the predicate for all handpieces. The proposed device met the specification and performance characteristics as identified in design control procedures. The energy related specifications of the subject device were found comparable to the corresponding specifications of the predicate device. The performance tests included but not limited to were the measurement of laser wavelength, pulse width, terminal maximum single pulse energy, repeat pulse frequency, spot diameter, micro-beam diameter, and energy per microbeam.

7.4 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. Animal testing

Animal studies were provided to show that the device can remove black tattoos as safely and as effectively as the predicate device.

9. Clinical data

NA.

10. Conclusion

The subject device and the predicate device have the same intended use and comparable technological characteristics. The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device (K210226) and supports a determination of substantial equivalence.