January 12, 2026

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

Re: K251988
Trade/Device Name: Boston iFace (Boston iFace)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: November 30, 2025
Received: December 10, 2025

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 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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.01.12 17:11:10 -05'00'

For
Colin Kejing Chen, Ph.D.
Acting 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.	K251988

Please provide the device trade name(s).

Boston iFace (Boston iFace)

Please provide your Indications for Use below.

The Boston iFace is intended to be used for heating to rise tissue temperature, which is used for selected medical conditions, such as temporary relief of pain, muscle spasms, and promotion of local circulation.

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

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

510(k) Summary

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

1. Administrative Information

Submission Date

November 06, 2025

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 iFace
Model:	Boston iFace
Regulation Description:	Electrosurgical Cutting And Coagulation Device And Accessories
Regulation Medical Specialty:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400
Product Code:	PBX, GEI
Device Class:	Class II

3. Predicate Device

510(K) Number:	K211639
Device name:	BTL-785W
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	Class II
Regulation Medical Specialty:	General & Plastic Surgery
Product code:	PBX, GEI
Regulation number:	21 CFR 878.4400

4. Reference Device

510(K) Number:	K241832
Device name:	Unicorn+ RF System
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	Class II
Regulation Medical Specialty:	General & Plastic Surgery
Product code:	PBX, GEI
Regulation number:	21 CFR 878.4400

510(K) Number:	K222556
Device name:	BTL-785X
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	Class II
Regulation Medical Specialty:	General & Plastic Surgery
Product code:	PBX, GEI
Regulation number:	21 CFR 878.4400

5. Device Description

The Boston iFace is mainly composed of a host, a footswitch, a handpiece, a hand swtich, a power cord, tip connectors, tips and a trolley.

The Boston iFace is a state-of-the-art radiofrequency device that enables the application of therapy by a high-frequency field. The control unit of the system is equipped with a large color touch screen that significantly facilitates the use of the device. The on-screen information guides the user step-by-step through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen of the device. During the therapy the device displays information about the applied therapy type, remaining therapy time and main therapy parameters on the screen. For easier control, the hand-pieces are equipped with buttons, enabling operation of the device during therapy.

5. Indication for Use

The Boston iFace is intended to be used for heating to rise tissue temperature, which is used for selected medical conditions, such as temporary relief of pain, muscle spasms, and promotion of local circulation.

6. Summary of Non-Clinical performance Testing

6.1. Electromagnetic Compatibility and Electrical Safety Test

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

IEC 60601-1
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances-Requirements and tests

IEC 60601-2-2
Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories

6.2. 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:

- In Vitro Cytotoxicity Test: ISO 10993-5: 2009
- Skin Irritation Test: ISO 10993-23:2021
- Skin sensitization Test: ISO 10993-10:2021

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

6.3. Software

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.

6.4. Bench Performance Testing

Bench performance testing was conducted to evaluate the functional performance of the subject device and to support its safety and effectiveness. The testing included evaluation of:

- Output power
- Operating frequency
- Temperature protection functions
- Thermal effects
- Skin surface temperature

Bench testing was performed under normal and worst-case operating conditions. The results demonstrated that the subject device performs as intended and does not raise new questions of safety or effectiveness when compared to the predicate device.

7. 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 (K211639) and supports a determination of substantial equivalence.