



September 22, 2026

Bh Group Us, LLC
Diego Bazzurro
Manager
10380 W. Sr 84 #7
Davie, Florida 33324

Re: K243223

Trade/Device Name: Multiple therapy aesthetic treatment device (BHS 202 UNYQUE)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 24, 2026
Received: August 25, 2026

Dear Diego Bazzurro:

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,

Colin K.
Chen -S

Digitally signed by
Colin K. Chen -S
Date: 2026.09.22
17:33:10 -04'00'

Colin K. Chen, Ph.D.
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

Form Approved: OMB No. 0910-0120

Expiration Date: 07/31/2026

See PRA Statement below.

Indications for Use

Submission Number (if known)

K243223

Device Name

Multiple therapy aesthetic treatment device (BHS 202 UNYQUE)

Indications for Use (Describe)

The multi-therapy aesthetic treatment device is designed to apply cold and radiofrequency. Radiofrequency hand piece raises tissue temperature to treat specific medical conditions, including relieving pain, relieving muscle spasms, improving local blood circulation, and temporarily improving the appearance of cellulite.

The multi-therapy aesthetic treatment device is intended for prescription use only, as defined in 21 CFR 801 Subpart D.

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.

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510(k) #: K243223

510(k) Summary

Prepared on: 2026-09-16

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	BH GROUP US, LLC
Applicant Address	10380 West SR 84 #7 Davie FL 33324 United States
Applicant Contact Telephone	305-497-3330
Applicant Contact	Mr. Diego Bazzurro
Applicant Contact Email	bhgroupus@gmail.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Multiple therapy aesthetic treatment device (BHS 202 UNYQUE)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Massager, Vacuum, Radio Frequency Induced Heat
Regulation Number	878.4400
Product Code(s)	PBX

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202780	Sectum System	PBX
K150035	V10 system(V-ST Handpiece)	PBX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The system includes a main control console and one applicator. The main body houses electronic and hydraulic components. The applicator is connected to the main console and mounted on dedicated holder. The front panel includes a user interface display. The system operates with RF energy through the respective handpiece.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The multi-therapy aesthetic treatment device is designed to apply cold and radiofrequency. Radiofrequency hand piece raises tissue temperature to treat specific medical conditions, including relieving pain, relieving muscle spasms, improving local blood circulation, and temporarily improving the appearance of cellulite. The multi-therapy aesthetic treatment device is intended for prescription use only, as defined in 21 CFR 801 Subpart D.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The intended use of the subject device is to deliver radiofrequency energy to elevate tissue temperature for the treatment of selected medical conditions, including pain relief, reduction of muscle spasms, enhancement of local blood circulation, and temporary

improvement in the appearance of cellulite.

This indication is substantially equivalent to those of the predicate devices:

- Sectum System (K202780) provide topical heating for the same purposes (pain relief, muscle spasm reduction, improved circulation, and temporary cellulite reduction).
- Viora V10 (K150035) is indicated for temporary pain relief, muscle spasm reduction & local circulation improvement.

Therefore, the intended use and therapeutic mechanism of the subject and predicate devices are equivalent.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

All devices deliver radiofrequency (RF) energy to biological tissue to achieve controlled heating for therapeutic or aesthetic purposes. The mechanism of action -conversion of RF electrical energy into heat within the dermal and subdermal layers- is identical among all devices.

All systems use a bipolar RF, providing localized heating without tissue ablation or ionization.

All devices are intended for use in healthcare or professional aesthetic environments, under trained operator supervision.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Thermal performance testing demonstrated that the BHS 202 UNYQUE with the CryoFrequency applicator maintains skin surface temperature below the predefined safety limit of 45.0 °C under the tested labeled operating conditions, including the minimum and maximum RF power levels and the minimum and maximum CryoCooling levels. The maximum recorded skin surface temperature was 43.1 °C, and no thermal adverse events were observed. Thus, this report complies with the requirements established in Title 21 CFR Part 807, Subpart E, demonstrating that the devices are substantially equivalent to products already approved by the FDA and that they meet the safety and effectiveness criteria expected for medical devices with similar aesthetic and therapeutic purposes.