



May 22, 2025

Inbella Medical Inc.
Michael Kreindel
CTO
100 Leek Crescent, unit 13
Richmond Hill, ON L4B 3E6
Canada

Re: K250200
Trade/Device Name: InbellaBody System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI

Dear Michael Kreindel:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 11, 2025. Specifically, FDA is updating this SE Letter to correct a typo in the company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact James Jang, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 240-402-6678, James.Jang@fda.hhs.gov.

Sincerely,

James H.
Jang -S

Digitally signed by
James H. Jang -S
Date: 2025.05.22
21:41:28 -04'00'

James Jang, 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



February 11, 2025

Inbella Medical Ltd.
% Jodi K. Scott
Partner
Hogan Lovells US LLP
1601 Wewatta Street, Suite 900
Denver, CO 80202
U.S.

Re: K250200
Trade/Device Name: InbellaBody System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 23, 2025
Received: January 23, 2025

Dear Jodi K. Scott:

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: 2025.02.11
09:57:14 -05'00'

For

Long 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

Indications for Use

510(k) Number (if known)

K250200

Device Name

InbellaBody System with BellaTform Applicator

Indications for Use (Describe)

The InBellaBody System with BellaTform Applicator employs RF technology and EMS-TENS technology for the treatment of selected medical conditions.

The BellaTform Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The BellaTform Applicator in EMS mode is intended for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

The BellaTform Applicator in TENS mode is intended for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

Additionally the BellaTform Applicator in sequential RF/EMS mode is intended for:

- Non-invasive lipolysis (breakdown of fat) of the abdomen.
- Reduction in circumference of the abdomen

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) SUMMARY**INBELLA MEDICAL INC.'S INBELLABODY SYSTEM WITH BELLATFORM APPLICATOR****Applicant Name:**

Company Name: Inbella Medical Inc.

Address: 100 Leek Crescent, unit 13,
Richmond Hill,
Ontario, Canada

Contact Person: Jodi K. Scott
Partner
jodi.scott@hoganlovells.com
T +1 303 899 7300454 2463
F +1 303 899 7333

Date Prepared: January 23, 2025

Name of Device: InBellaBody System with BellaTform Applicator

Common or Usual Name: Radiofrequency-based electrosurgical coagulation device

Classification Name: CFR Classification section 878.4400

Classification: Class II Medical Device

Product code: GEI

Predicate Device:

The InBellaBody System with BellaTform Applicator manufactured by Inbella Medical is substantially equivalent to the Evolve System with Transform Applicator manufactured by InMode Ltd. (K231495).

Purpose of the 510(k) notice:

The InBellaBody System with BellaTform Applicator manufactured by Inbella Medical is identical in all aspects to the Evolve System with Transform Applicator manufactured by InMode Ltd. (K231495). The only difference is the manufacturer and 510(k) holder.

Intended Use:

The InBellaBody System with BellaTform Applicator employs RF technology and EMS-TENS technology for the treatment of selected medical conditions.

The BellaTform Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The BellaTform Applicator in EMS mode is intended for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
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- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

Additionally the BellaTform Applicator in sequential RF/EMS mode is intended for:

- Non-invasive lipolysis (breakdown of fat) of the abdomen.
- Reduction in circumference of the abdomen

Device Description:

The InBellaBody System with BellaTform Applicator is designed to deliver non-thermal RF energy and electro-muscle and transcutaneous nerve stimulation for the treatment of different body areas for various medical applications. The InBellaBody System software controls and regulate the different applied energies in accordance with the user system preprogramming and treatment settings.

The InBellaBody System System includes the following components:

- LCD display touch screen,
- Audio loudspeaker,
- 48V AC/DC power supply,
- Real time controller, distributor card and 2 RF generators,
- Fans

The System operates while connected to the BellaTform Applicator.

Performance Standards:

The InBellaBody System with BellaTform Applicator has been tested and complies with the following voluntary recognized standards:

- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 60601-1-2 Edition 4.0 2014-02 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 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

Non-Clinical (Bench) Performance Data:

Not Applicable

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of InBellaBody System with BellaTform Applicator manufactured by Inbella Medical are the same as those of the Evolve System with Transform Applicator manufactured by InMode Ltd. (K231495). The only difference is the manufacturer and 510(k) holder.

Thus, the InBellaBody System with BellaTform Applicator is substantially equivalent to the cleared predicate and may, therefore, be legally marketed in the USA.