October 15, 2025

Inbella Medical Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K252367
Trade/Device Name: InbellaMulti System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 29, 2025
Received: July 30, 2025

Dear Janice Hogan:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.15 13:36:54 -04'00'

Colin Kejing Chen
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.	K252367

Please provide the device trade name(s).

InbellaMulti System

Please provide your Indications for Use below.

The InbellaMulti System with the Non-invasive Applicators employs RF energy for various applications:

• i-BellaForma, BellaForma, BellaPlus and BellaPlus90
for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

•BellaWMface is intended for use in dermatologic procedures for non-invasive treatment of mild to moderate facial wrinkles and rhytids.

• BellaBodyFX /BellaMiniFX for Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and temporary reduction in the appearance of cellulite.

The InbellaMulti System with the Fractional Applicators employs RF energy for various applications:

• BellaFractora Applicator with 60 pins tip is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

• BellaFractora Applicator with 24 pins tip is intended for use in dermatological and general surgical procedures for
electrocoagulation and hemostasis. At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

• BellaM8 for dermatologic procedures where coagulation/contraction of soft tissue or hemostasis is needed. At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

INBELLA MEDICAL INC.'S INBELLAMULTI SYSTEM

Applicant Name:

Company Name: Inbella Medical Inc.

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

Contact Person: Janice M. Hogan
Partner
janice.hogan@hoganlovells.com
T +1 267 675 4611
F +1 267 675 4601

Date Prepared: July 29, 2025

Name of Device: InBellaMulti System

Common or Usual Name: Radiofrequency-based electrosurgical coagulation device

Classification Name: 21 CFR 878.4400

Classification: Class II Medical Device

Product Code: GEI

Predicate Device:

The InBellaMulti System manufactured by Inbella Medical, Inc. (platform and all applicators other than BellaM8) is substantially equivalent to the InMode RF Pro System cleared in K210492 by InMode Ltd. For the BellaM8 applicator, the subject device is substantially equivalent to the InMode System with Morpheus8 applicators cleared in K231790 by InMode Ltd.

Purpose of the 510(k) Notice:

The InBellaMulti System manufactured by Inbella Medical, Inc. is identical in all aspects to the listed predicate devices. The only difference are the manufacturer and 510(k) holder, as well as system and related handpiece names.

Intended Use:

The **InbellaMulti** System with the Non-invasive Applicators employs RF energy for various applications:

- **i-BellaForma, BellaForma, BellaPlus and BellaPlus90** for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

•**BellaWMface** is intended for use in dermatologic procedures for non-invasive treatment of mild to moderate facial wrinkles and rhytids.

• **BellaBodyFX /BellaMiniFX** for relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and temporary reduction in the appearance of cellulite.

The **InbellaMulti** System with the Fractional Applicators employs RF energy for various applications:

• **BellaFractora** Applicator with 60 pins tip is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

• **BellaFractora** Applicator with 24 pins tip is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

• **BellaM8** for dermatologic procedures where coagulation/contraction of soft tissue or hemostasis is needed. At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

Except for the difference in device name and applicator names, the indications for use of the subject device are identical to those of the predicate applicators in K210492 for all applicators except for the BellaM8 applicators. The indications for the BellaM8 applicators are identical to those cleared more recently in K231790 for the Morpheus8 applicators.

Device Description:

The InbellaMulti System supports multiple radiofrequency (RF) applications and accessories. The InbellaMulti System is compatible with the Fractional RF Applicators and the Non-Invasive RF Applicators, and employs RF energy for various applications. The InbellaMulti System consists of a platform console with an AC/DC power supply unit, two applicator connectors, RF generator, RF measuring circuit, controller, footswitch and user interface including a touch screen. The RF Applicator is connected to the console via a cable and a footswitch activates the energy delivery to the applicator. The applicators are comprised of a handle and electrodes, and some of them are used with a single-use tip. The below list comprises the set of applicators to be registered under the subject device:

- i-BellaForma
- BellaForma
- BellaPlus
- BellaPlus90
- BellaWMFace
- BellaBodyFX
- BellaMiniFX
- BellaFractora with 60 pins tip
- BellaFractora with 24 pins tip
- BellaM8 with the following tip heads: Resurfacing (T) , Prime (12-pin), 24-pin, 40-pin (Body)

The technological characteristics of the subject device are identical to those of the predicate applicators in K210492 for all applicators except for the BellaM8 applicators. The technological

characteristics for the BellaM8 applicators are identical to the Morpheus8 applicators cleared more recently in K231790.

Performance Standards:

The InBellaMulti System 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 the InBellaMulti System manufactured by Inbella Medical, Inc. are the same as those of the InMode System manufactured by InMode, Ltd. The only difference are the manufacturer and 510(k) holder, as well as system and related handpiece names.

Thus, the InbellaMulti System is substantially equivalent to the cleared predicate and may, therefore, be legally marketed in the USA.