May 22, 2025

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

Re: K243737
Trade/Device Name: Inbella RF 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 January 3, 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 22:15:31 -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

January 3, 2024

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

Re: K243737
Trade/Device Name: Inbella RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 19, 2024
Received: December 19, 2024

Dear Michael Kreindel:

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: 2025.01.03 18:03:15 -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

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)*
K243737

Device Name
Inbella RF System

Indications for Use *(Describe)*
The Inbella RF System is indicated for use in dermatological and general surgical procedures where coagulation/contraction of soft tissue or hemostasis is needed.

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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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Inbella Medical Inc.'s
Inbella RF System

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 +1 303 454 2463
F +1 303 899 7333

Date Prepared: December 4, 2024

Name of Device: **Inbella RF System**

Common or Usual Name: Radiofrequency-based electrosurgical coagulation device

Classification Name: CFR 878.4400

Regulatory Class: Class II Medical Device

Product Code: GEI

Predicate Device:

The Inbella RF System manufactured by Inbella Medical is substantially equivalent to the InMode RF System manufactured by InMode Ltd. (K240780).

Purpose of the 510(k) notice:

The Inbella RF System manufactured by Inbella Medical is identical in all aspects to the InMode RF System manufactured by InMode Ltd. (K240780). The only difference is the manufacturer and 510(k) holder.

Intended Use:

The Inbella RF System is indicated for use in dermatological and general surgical procedures where coagulation/contraction of soft tissue or hemostasis is needed.

Device Description:

The Inbella RF System is a computerized system generating RF energy with integral temperature and impedance feedback mechanism for procedures requiring electrocoagulation/contraction of soft tissue and hemostasis. The Inbella RF System constantly monitors the temperature and impedance of the

target treatment tissue, automatically adjusting energy delivery to maintain effective and safe tissue heating. The Inbella RF System consists of an AC/DC power supply unit, RF generator, controller and user interface including touch screen. The RF handpiece is connected to the console via a cable and a foot switch activates the energy delivery to the handpiece. Multiple handpieces are available, all comprised of a disposable, single use plastic handle with active internal electrodes. A subset of handpieces have both internal (active) and external (return) electrodes.

Performance Standards:

The Inbella RF 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 60601-1-2 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:

No new bench performance data is submitted to support this submission.

Animal Performance Data / Histology Data:

No new animal performance data is submitted to support this submission.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the Inbella RF System manufactured by Inbella Medical are the same as those of the InMode RF System manufactured by InMode Ltd. (K240780). The only difference is the manufacturer and 510(k) holder.

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