November 20, 2024

INDIBA S. A. U.
Nieves Arias Badia
HHRR, Legal and Regulatory Affairs Director
Carrer del Moianès, 13
Sant Quirze del Vallès, BCN 08192
Spain

Re: K243164
Trade/Device Name: INDIBA COMPACT devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: September 27, 2024
Received: September 30, 2024

Dear Nieves Arias Badia:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.20 13:58:00 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243164

Device Name

INDIBA COMPACT devices

Indications for Use *(Describe)*

INDIBA COMPACT devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms and increase in local circulation.

The massage electrodes are intended to provide a temporary reduction in the appearance of cellulite.

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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SECTION 05 – 510(k) SUMMARY

DATE OF SUBMISSION: 2024-09-27
SUBMITTER NAME: INDIBA S. A. U.
SUBMITTER ADDRESS: Carrer del Moianès, 13
08192 Sant Quirze del Vallès, Barcelona
Spain

CONTACT: Nieves Arias Badia
TELEPHONE: +34 932 655 522
e-mail: regulatory@indiba.com

DEVICE TRADE NAME: INDIBA COMPACT Devices
COMMON NAME: Radiofrequency device
REGULATION DESCRIPTION: Electrosurgical cutting and coagulation device and accessories
CLASS: Class II
REGULATION NUMBER: 21 CFR 878.4400
PRODUCT CODE: PBX

PREDICATE DEVICE
Predicate device:

K161458	Indiba Diathermia Radiofrequency Device

DEVICE DESCRIPTION:

The INDIBA COMPACT devices are therapeutic devices for deep, non-invasive diathermy. The device consists of a console which generates a radiofrequency current which is delivered to the patient, in monopolar form, through two different types of electrodes: stainless steel conductive resistive electrodes, and thin-layer insulated capacitive electrodes. The electrodes are inserted into a handle/handpiece, one handle for each kind of electrode, and the handle is connected to the console by means of a cable.

In resistive mode the system delivers a high- frequency current of 448 kHz directly to the patient's skin surface. In capacitive mode, the electrode coating creates a layer between the electrode and the human tissue, forming a capacitor that allows a high-frequency current at 448 kHz to pass. Current returns through the neutral return electrode.

INDIBA Compact devices are provided with an electroconductive media which is applied to the patients' skin prior to each treatment session. The RF energy generates a heating profile that produces a moderate temperature rise in the subcutaneous tissue. In Compact Lite, the temperature on the skin is measured using a separate IR (Infra-red) thermometer and in Compact Plus and Compact Pro

SECTION 05 – 510(k) SUMMARY

temperature is measured through the smart electrodes and smart handle, which inform of the surface skin temperature trough a color scale. There are also other accessories available as massage electrodes with different shapes that can be used to massage the skin during cellulite treatment.

INTENDED USE / INDICATIONS FOR USE:

As established in the Indications for Use Statement:

INDIBA COMPACT devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms and increase in local circulation. The massage electrodes are intended to provide a temporary reduction in the appearance of cellulite.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The INDIBA COMPACT Devices are substantially equivalent to the primary predicate device (INDIBA Diathermia Radiofrequency Devices, K161458) in intended use/indications and in important physical and performance specifications. The subject and predicate device are substantially equivalent in design, features, and material. The subject device was subjected to the following bench performance tests to support the assertation of substantial equivalence and evidence that no new safety or effectiveness concerns were raised:

- Electrical safety
- Electromagnetic compatibility

In addition to the electrical safety testing performed, software verification and validation was conducted to IEC 62304: 2006 – Medical device software – Software Life-Cycle Processes, and FDA guidance on software validation. The results of this testing conclude the software has met these requirements.
Patient contacting materials have been evaluated according to the requirements of ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing and confirmed to be biocompatible for their intended use.

SUMMARY DISCUSSION OF CLINICAL DATA:

Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence. No clinical studies are submitted.

SECTION 05 – 510(k) SUMMARY

SUMMARY OF SUBSTANTIAL EQUIVALENCE DISCUSSION:

The subject and predicate device are substantially equivalent in design, features, and material. The technological characteristics of INDIBA COMPACT Devices raise no new issues related to safety and effectiveness. Based on the information provided in this submission, INDIBA COMPACT Devices are substantially equivalent to the predicate device (K161458).

CONCLUSIONS:

The design characteristics, material and intended use of the INDIBA COMPACT Devices are substantially equivalent to the predicate device INDIBA Diathermia Radiofrequency Devices (K161458). The safety and effectiveness of INDIBA COMPACT Devices are adequately supported by the substantial equivalence information, materials information and performance data provided within this Premarket Notification submission.