DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 3, 2016

Indiba USA Inc.
% Mr. Howard Beaumont
Indiba S.A.
13 - Pol. Ind. Casablancas
Sant Quirze Del Valles, Barcelona, Spain 08192

Re: K161458
Trade/Device Name: Indiba Diathermia Radiofrequency Device - Activ; Indiba Diathermia Radiofrequency Device - Deep Care
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 20, 2016
Received: August 26, 2016

Dear Mr. Beaumont:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161458

Device Name
Indiba Diathermia Radiofrequency Devices

Indications for Use *(Describe)*
The Indiba Diathermia Radiofrequency 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, increase in local circulation.
The massage device provided is 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.

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SECTION 06 – 510(k) SUMMARY

Contact Details

510(k) Number	K161458
Applicant:	Indiba USA Inc. 1717 Embarcadero Road Palo Alto CA 94303 USA
Applicant Contact:	Carles Janer Regulatory Affairs Manager
C/O Applicant:	Indiba S.A. C / Moianés 13 - Pol. Ind. Casablancas 08192 Sant Quirze del Vallés Barcelona Spain
Application Correspondent:	Howard Beaumont Regulatory Affairs Consultant
Date Prepared	18th May 2016

Device Details

Common Name:	Radiofrequency Device
Device Trade Name	Indiba Diathermia Radiofrequency Device
Classification Name:	Electrosurgical, cutting and coagulation accessories
Regulation Number:	878.4400
Product Code	PBX
Device Class:	2
Panel:	General & Plastic Surgery

Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Applicant
K133739	PBX, 878.4400	TruSculpt	Cutera Inc.
K132949	PBX, 878.4400	PelleFirm System	Ellman International (Cynosure Inc.)

Device Description

The Indiba Diathermia Radiofrequency Device is a therapeutic device 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 2-metre 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 to pass. The high frequency current ranges between 400 kHz and 449 kHz and is automatically tuned by the equipment according to the patient's impedance. Current returns through the neutral return electrode. The Indiba Diathermia Radiofrequency Device is 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.

The temperature on the skin is measured using a separate IR (Infra-red) thermometer and there is an integrated massage device that can be used to massage the skin during cellulite treatment.

Indications for Use

The Indiba Diathermia Radiofrequency 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, increase in local circulation.

The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.

Technical Characteristics

Characteristic	Value / Description
Input voltage supply :	(100 – 130) V~ 50/60 Hz
Temperature range for operation :	+10ºC to +40ºC
Temperature range for storage and transport :	-20ºC to +50ºC
Timer range :	0 – 99 minutes
Display :	5.7 inch TFT color 320 x 240 pixels
Other features :	- Output protected against accidental short-circuit between neutral plate and active electrode. - Output over-voltage limitation - Output over-power limitation - Contact detection with patient skin - Internal over-temperature protection

Substantial Equivalence

The indications for use, functionality, type of application, type of electrodes, skin temperature sensing and compliance to safety standards of the Indiba Diathermia Radiofrequency Device are the same or very similar to the legally marketed, claimed predicate devices for the purpose of this 510(k) submission. Technological differences between the Indiba Diathermia Radiofrequency Device and the predicate devices are limited to small variations in the maximum power (200 W, while predicate devices have a range from 120 W to 300 W) and the RF frequency (400 kHz - 449 kHz, while the predicate device has a range of 300 kHz – 50 MHz). Also, the patient contacting materials of the Indiba Diathermia Radiofrequency Device are different to those of the predicate devices, but are biocompatible for their intended purpose.

Non-Clinical Testing

The Indiba Diathermia Radiofrequency Devices have been tested and are in compliance with IEC/EN 60601-1:2005+ Corr. 2006, Medical electrical equipment. Part 1: General requirements for basic safety and essential performance, IEC/EN60601-1-2:2007+AC:2010 Medical electrical equipment. Part 1: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests, and applicable sections of IEC 60601-2-2: 2009 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. 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 ISO10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing, and confirmed to be biocompatible for their intended use.

Design verification and validation was also performed on the Indiba Diathermia Radiofrequency Devices in compliance with internal design control procedures.

The electrical output characteristics of the Indiba Diathermia Radiofrequency Devices have been tested to demonstrate the devices meet the stated performance characteristics. The Output Characteristic testing measured output frequency, output voltage and output power at 100% (3 resistance loads). The results for each tested output characteristic for all the Indiba Diathermia Radiofrequency Devices passed the acceptance criteria. The testing concluded that each output characteristic for each device in the range was within the stated performance characteristics specification.

Clinical Evaluation

Clinical investigations were not conducted to support substantial equivalence.
An independent search, review and analysis of published and un-published

literature to support the claim that the Indiba Diathermia Radiofrequency Devices are safe and effective was conducted. For the purpose of the evaluation of the literature, publications pertaining to RF applications under the indications for: relief of pain, relief of muscle spasms, increase in local circulation and temporary reduction in the appearance of cellulite, were sought. The independent evaluation concluded that there was supportive evidence that the Indiba family of devices, delivering RF energy in resistive and capacitive modes, can achieve a significantly beneficial effect on ache/pain, local circulation, cellulite and the relief of muscle spasm.

Indiba Diathermia Radiofrequency Devices have been validated in an in-house study on healthy volunteers to demonstrate that the Indiba Diathermia Radiofrequency Devices increase skin surface temperature to the range 40-45^{O}C.

The study was conducted on nine healthy volunteers, in accordance with Indiba Diathermia Radiofrequency Device standard treatment protocols, with treatment applied to the middle third of the anterior right thigh. Each session consisted of a combination of application of the capacitive electrode followed by the resistive electrode. Prior to each session electroconductive media was applied to the area of skin to be treated. Treatment times were approximately 5-6mins capacitive followed by 7-11mins resistive. Skin surface temperature was recorded using an Infrared Thermometer.

Tolerance of the treatment was good, there were no reports of discomfort and there were no requirements to adjust the treatment powers. Mild transitory erythema (skin reddening) was present in all volunteers in temperatures around 42-43 °C.

The results confirmed that individual volunteers' maximum temperatures on capacitive treatment were 41-44 °C and on capacitive and resistive were 41-43 °C.

The validation confirmed that after a minimum of 5 minutes the Indiba Diathermia Radiofrequency Device can raise, and maintain, the skin temperature to the range of 40-45 °C under capacitive and resistive applications.

Conclusion

The results of external and in-house testing, and the conclusions of the independent review of literature, summarised above, demonstrate that the Indiba Diathermia Radiofrequency Devices are safe and effective and are substantially equivalent to the predicate devices in terms of performance.