January 29, 2019

Wintecare SA
Mr. Claudio Freti
Director
Via Livio 12
6830 Chiasso
Switzerland

Re: K181893
Trade/Device Name: T-plus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: January 10, 2019
Received: January 16, 2019

Dear Mr. Freti:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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: 2019.01.29 08:51:50 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181893

Device Name
T~PLUS

Indications for Use *(Describe)*
The T~PLUS is 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.

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510(k) Summary

1. Sponsor/ Applicant

Wintecare SA
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6830 Chiasso
Switzerland

Mr. Claudio Freti
Position: CEO/Director
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Summary Preparation Date: January 24, 2019

2 . Device

Trade Name	T~PLUS
Classification	Class II
Product Code	PBX
Regulation Number	21 CFR 878.4400
Review Panel	General & Plastic Surgery

3 . Predicate Device

- Indiba Diathermia Radiofrequency Device - Activ; Indiba Diathermia Radiofrequency Device - Deep Care (K161458)

4 . Device Description

The Wintecare T~PLUS is a device for diathermy / Tecar therapy. It consists of a control unit which generates a radiofrequency current which is delivered to the patient, through two different types of electrodes: stainless steel conductive resistive electrodes, and thin-layer insulated capacitive electrodes. The electrodes are inserted into a smart handle/handpiece, one handpiece for each kind of electrode, and the handpiece is connected to the control unit by means of a 2-metre cable.

In resistive mode the system delivers a high-frequency current of 447 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 is automatically tuned by the equipment according to the patient's impedance. Current returns through the indifferent return electrode. The RF energy generates a heating profile that produces a moderate temperature rise in the subcutaneous tissue.

The use of Wintecare Conductive A+ Cream is recommended on the patients' skin prior to each treatment session with the T~PLUS. The cream is offered with the T~PLUS and is part of this 510(k) submission.

5 . Indications for Use

The T~PLUS is 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.

6. Technological Characteristics and Substantial Equivalence

The proposed T~PLUS is substantially equivalent to the referenced predicate device in regard to the intended use, fundamental scientific technology, and technological characteristics, as outlined in the following table:

Table 1: Substantial Equivalence Comparison between T~PLUS and the Predicate Device

Characteristic	**Subject Device**	**Predicate Device**
Trade Name	**T~PLUS**	**Indiba Diathermia Radiofrequency Device - Activ; Indiba Diathermia Radiofrequency Device - Deep Care**
Submitter	Wintecare, SA	Indiba USA Inc.
Classification	Device Class: 2 Product Code: PBX 21 CFR 878.4400	Device Class: 2 Product Code: PBX 21 CFR 878.4400

Indications for Use	The T~PLUS is 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.	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

Characteristic	**Subject Device**	**Predicate Device**
Trade Name	**T~PLUS**	**Indiba Diathermia Radiofrequency Device - Activ; Indiba Diathermia Radiofrequency Device - Deep Care**
Prescription / Over-TheCounter (OTC) Use	Prescription Use	Prescription Use

Device Description	The Wintecare T~PLUS is a device for diathermy / Tecar therapy. It consists of a control unit which generates a radiofrequency current which is delivered to the patient, through two different types of electrodes: stainless steel conductive resistive electrodes, and thin layer insulated capacitive electrodes. The electrodes are inserted into a smart handle/handpiece, one handpiece for each kind of electrode, and the handpiece is connected to the control unit by means of a 2metre cable. In resistive mode the system delivers a high-frequency current of 447 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 is automatically tuned by the equipment according to the patient's impedance. Current returns through the indifferent return electrode. The RF energy generates a heating profile that produces a moderate temperature rise in the subcutaneous tissue. The Wintecare Conductive A+ Cream is recommended to be used on the patients' skin prior to each treatment session.	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 2metre 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.
Characteristic	**Subject Device**	**Predicate Device**
Trade Name	**T~PLUS**	**Indiba Diathermia Radiofrequency Device - Activ; Indiba Diathermia Radiofrequency Device - Deep Care**
Display/ User Interface	5.7 inch TFT color 320 x 240 pixels	5.7 inch TFT color 320 x 240 pixels
Technical Specifications		

<table>
<tr><td>Timer range</td><td>3 – 90 minutes</td><td>0 – 99 minutes</td></tr>
<tr><td>Output Frequency</td><td>447 kHz</td><td>448 ± 1 kHz</td></tr>
<tr><td>Input voltage supply</td><td>100 - 240 V, 50/60 Hz</td><td>100 – 130 V, 50/60 Hz</td></tr>
<tr><td>Output Power Rating</td><td>RES: 300W CAP:
450VA</td><td>Indiba Devices
<table><tr><th></th><th>activ 7</th><th>activ CT8</th><th>active CT9</th></tr><tr><td>RES</td><td>65 W</td><td>100 W</td><td>200 W</td></tr><tr><td>CAP</td><td>250 VA</td><td>350 VA</td><td>450 VA</td></tr></table>
<table><tr><th></th><th>Deep are ELITE</th><th>Deep Care ELITE NS</th><th>Deep Care RGN</th></tr><tr><td>RES</td><td>200 W</td><td>200 W</td><td>65 W</td></tr><tr><td>CAP</td><td>450 VA</td><td>450 VA</td><td>250 VA</td></tr></table></td></tr>
<tr><td>Operating temperature</td><td>+10ºC to +40ºC</td><td>+10ºC to +40ºC</td></tr>
<tr><td>Storage and Transport temperature</td><td>-40ºC to +70ºC</td><td>-20ºC to +50ºC</td></tr>
<tr><td>Conformity to Standards</td><td></td><td></td></tr>
<tr><td>Electrical Safety</td><td>60601-1
60601-2-2: Medical electrical equipment. Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.</td><td>60601-1</td></tr>
<tr><td>EMC</td><td>60601-1-2</td><td>60601-1-2</td></tr>
</table>

7 . Non-clinical Bench (Performance) testing

The Electrical Safety and Electromagnetic Compatibility of the T~PLUS is demonstrated through testing conducted in compliance with standards IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2, respectively.

In addition, the Biocompatibility of the electrodes and conductive cream used with the T~PLUS is demonstrated through testing conducted per standards ISO 10993-5 and ISO 10993-10.

With regard to the conductive cream, evidences of ingredients' correspondence between the INCI UE classification and INCI US classification as well as IUPAC nomenclature have been demonstrated.

8. Clinical Testing

The submission also contains data from clinical testing, demonstrating the ability of the T~PLUS to maintain therapeutic temperature for at least 10 minutes on patients, between 40° and 45° C, never exceeding 45° C.

9. Conclusion:

Based on the intended use, design, technological characteristics and performance data provided in the submission, clinical and non-clinical testing the T~PLUS device is substantially equivalent to the referenced predicate devices.