May 25, 2023

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Consultant
Quality and Regulatory Services
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K213256
Trade/Device Name: ThermoTK
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: May 5, 2023
Received: May 8, 2023

Dear Scott Blood:

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/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 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 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.25 10:01:22 -04'00'

Mark Trumbore, 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)*
K213256

Device Name
ThermoTK

Indications for Use *(Describe)*
The ThermoTK device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

The ThermoTK massage device 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"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."*

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# 510(k) Summary
# ThermoTK
# K213256

1. Basic Information-Submitter:

| | |
|---|---|
| 510(k) Owner: | Zimmer MedizinSysteme GmbH<br>Junkersstrasse 9<br>89231 Neu-Ulm<br>Germany<br>Establishment Registration: 8010720 |
| Official Contact: | Mrs. Ute Hauss<br>Manager Regulatory Affairs<br>Phone: +49-731-9761-216<br>Fax: +49-731-9761-118<br>E-mail: u.hauss@zimmer.de |
| Date Summary Prepared: | September 29, 2021 |

2. Device Name:

| | |
|---|---|
| Trade Name: | ThermoTK |
| Common Name: | Massager, Radio Frequency Induced Heat |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories |
| Regulation Number: | 21 CFR 878.4400 |
| Product Code: | PBX |
| Classification: | Class II |

3. Predicate Device: Winback Back 3SE – K162828
   Company Name: WINBACK USA Corp

4. Device Description:

ThermoTK is a medical diathermy device for external tissue heating on the human skin with the purpose of increasing tissue temperature by applying electromagnetic fields of 460 or 540 KHz.

The device includes a plastic housing with a capacitive touch display which guarantees an easy handling to select and start a treatment. In this housing, an electronic power module is implemented which drives the electromagnetic energy into the connected handpiece. By using the two adjusters, it is possible to set the treatment intensity and treatment time. Two handpieces for two different treatment modes are attached and can be connected to the control unit depending on which treatment mode the therapy has to be performed. An

electrode (resistive or capacitive) has to be plugged on the handpiece for treatment. The device also includes two different electrode cables which can be connected with attached common electrodes (self-adhesive or reusable). For a better stability while using the handpiece during application, a silicone spacer can be put between handpiece and electrode.

**Indications for Use Statement**:

ThermoTK is indicated to be used for:

Provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

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

| ATTRIBUTE | SUBJECT DEVICE<br>Zimmer MedizinSysteme GmbH<br>ThermoTK<br>This Submission | PREDICATE DEVICE<br>WINBACK USA Corp<br>Winback Back 3SE<br>K162828 |
|---|---|---|
| Indications for Use | General & Plastic Surgery<br>21 CFR 878.4400<br>PBX – Massager, Radio Frequency Induced Heat | General & Plastic Surgery<br>21 CFR 878.4400<br>PBX – Massager, Radio Frequency Induced Heat |
| | The ThermoTK device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.<br><br>The ThermoTK massage device is intended to provide a temporary reduction in the appearance of cellulite. | The Winback Back 3SE device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.<br><br>The Winback Back 3SE massage device is intended to provide a temporary reduction in the appearance of cellulite. |

The Indications for Use statement for ThermoTK is identical to the predicate device.

5. Technological Characteristics:

Both devices are consoles with electrode accessories capable of operation in unipolar and multipolar modes of 460 kHz or 540 kHz radiofrequencies.

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Both devices operate in the same treatment range and voltage and feature intensity adjustments from 0-100%. Electrical safety and biocompatibility have been established for both devices. No direct comparison was made since there are no significant differences in operation and test results indicate identical safety.

The table below summarizes the equivalence of the devices.

| **Technological Characteristics** | **SUBJECT DEVICE Zimmer MedizinSysteme GmbH ThermoTK This Submission** | **PREDICATE DEVICE WINBACK USA Corp Winback Back 3SE K162828** |
|---|---|---|
| Massaging hand piece | Yes | Yes |
| Electrode Shapes | Rectangular and circular | Square and circular |
| Infrared Light | No | No |
| Vacuum (suction) | No | No |
| Treatment Activation | Finger selection on capacitive touch display and adjuster | Finger selection on console |
| RF Type | Multipolar/Unipolar | Multipolar/Unipolar |
| RF Frequency | 460 kHz or 540 kHz | 300 kHz – 1 MHz |
| Max RF Power | 115VA | 300 W |
| Intensity Adjustment | 0-100% | 0-100% |
| Configuration | Standalone console with accessories | Cart mounted console with accessories |
| Patient Safety Switch | No | Yes |
| Temperature Capacitive mode Resistive mode | Skin Temperature +1°C to max. 42°C ± 5% | 40°C – 43°C |
| Treatment Area | Whole body excepted those mentioned in the contraindications | Whole body excepted those mentioned in the contraindications |
| Operating modalities | Continuous Pulsed | Continuous Pulsed |
| Modes | Resistive Capacitive Hands-free | Resistive Capacitive |

| Technological Characteristics | SUBJECT DEVICE<br>Zimmer MedizinSysteme GmbH<br>ThermoTK<br>This Submission | PREDICATE DEVICE<br>WINBACK USA Corp<br>Winback Back 3SE<br>K162828 |
|---|---|---|
| Electrode dimensions | Resistive electrode:<br>Ø 30mm, 50mm,70mm<br><br>Capacitive electrode:<br>Ø 30mm, 50mm,70mm<br><br>Common electrode:<br>140mm x 240mm<br><br>Common electrode Self-adhesive:<br>105mm x 200mm | Resistive electrode:<br>Ø 40mm, 60mm,70mm<br><br>Capacitive electrode:<br>Ø 40mm, 60mm,70mm<br><br>Common electrode:<br>Not mentioned<br><br>Common electrode Self-adhesive:<br>Not mentioned |
| Safety features | Several output protections | Not publicly available |

There are no significant technological differences between the ThermoTK device and the predicate device. There are few and not significant technological differences between the subject device and the predicate device. Those differences have been discussed and do not affect device safety or performance. The subject device has all features of the predicate device. ThermoTK does not raise any new types of safety or effectiveness questions.

6. Performance data

The ThermoTK device has been investigated and tested against and complies with the following voluntary standards:

| Standards | Standards Organization | Standards Title |
|---|---|---|
| ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) | ANSI AAMI | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| 60601-1-2:2014 (Edition 4.0) | IEC | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests |
| 60601-1-6:2013 (Edition 3.1) | IEC | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| 62366-1:2015 (Edition 1.0) | IEC | Medical devices – Part 1: Application of usability engineering to medical devices |
| 62304:2015 (Edition 1.1) | IEC | Medical devices software –software life cycle processes |
| 14971:2019-12 (Edition 3.0) | ISO | Medical devices – Application of risk management to medical devices |
| 15223-1:2016 (Edition 3) | ISO | Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements |
| 10993-1:2018 (Edition 5) 10933-10 | ISO | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process |
| 10993-5:2009 (Edition 3) | ISO | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity |
| 10993-10:2010 (Edition 3) | ISO | Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization |

The following table shows a comparison of the performance testing in comparison to the predicate device:

| Standards | SUBJECT DEVICE<br>Zimmer MedizinSysteme GmbH<br>ThermoTK<br>This Submission | PREDCIATE DEVICE<br>WINBACK USA Corp<br>Winback Back 3SE<br>K162828 |
|---|---|---|
| ANSI AAMI 60601-1 | X | X |
| IEC 60601-1-2 | X | X |
| IEC 60601-1-6 | X | X |
| IEC 62366-1 | X | X |
| ISO 14971 | X | X |
| ISO 10993-1<br>ISO 10993-5<br>ISO 10933-10 | X | X |

According to this comparison table all required performance tests were conducted and show substantial equivalence with the predicate devices.

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

7. 510(k) Summary:

Zimmer MedizinSysteme GmbH has demonstrated that the ThermoTK device is substantially equivalent to the predicate device.