DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 18, 2017

WINBACK USA Corp
% David Furr
Regulatory Correspondent
FDC Services
8708 Capehart Cove
Austin, Texas 78733

Re: K162828
Trade/Device Name: Winback Back 3SE
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 13, 2017
Received: August 16, 2017

Dear David Furr:

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 -S3

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)*
K162828

Device Name
Winback Back 3SE

Indications for Use *(Describe)*
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. The Winback Back 3SE 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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 Pursuant to 21 CFR 807.92

Date: August 13, 2017
K162828

1. Submitted By: WINBACK USA Corp
302 High Plains Drive
Dripping Springs, TX 78620
323-898-2469

2. Contact: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: Winback Back 3SE
(21CFR§878.4400) Class II
Winback Back 3SE
Product code PBX

4. Common/Trade Name: Massager, Radiofrequency Induced Heat
Winback Back 3SE

Description:

The Winback Back 3SE generates a high frequency sinusoidal current with a monopolar mode of application using two electrodes. A fixed electrode is placed in contact with the patient and a handheld electrode is manipulated by a therapist. When both electrodes are in contact with a patient the electrical circuit is closed and RF therapy can be provided. The device can be operated in a capacitor resistive monopolar mode and a multipolar mode.

The product consists of a power console on a moveable trolley, LCD monitor, and accessories including capacitive resistive electrodes and multipolar electrodes. The unit can be adjusted to provide various levels of treatment frequency ranging from 300 KHz to 1 MHz.

Intended Use:

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. The Winback Back 3SE massage device is intended to provide a temporary reduction in the appearance of cellulite.

Substantial Equivalence/Technological Characteristics:

The Winback 3SE device is substantially equivalent to the following device:

- Predicate device clearance: K133739
- Trade Name: truSculpt
- Company: Cutera Incorporated

Both devices are cart mounted consoles with electrode accessories capable of operation in monopolar and multipolar modes in the range of 300kHz to 1MHz radiofrequency.

Both devices operate in the same treatment range and voltage and feature intensity adjustments from 0 to 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.

Predicate Device Comparison Table

Element of Comparison	**510(k) Device:** Winback 3SE	**Predicate Device:** truSculpt, Cutera Incorporated K133739	**Explanation of Differences**
Regulation and Product Classification Code	21 CFR 878.4400 PBX	21 CFR 878.4400 PBX	None
Indications for Use	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. The Winback Back 3SE massage device is intended to provide a temporary reduction in the appearance of cellulite.	The truSculpt RF energy 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 truSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite.	No significant difference for radiofrequency device.
Massaging Hand piece	Yes	Yes	Identical
Electrode Shapes	Square and circular	Square and rectangle	Electrode shape is not a significant difference
Infrared Light	No	No	Identical
Vacuum (suction)	No	No	Identical
Treatment Activation	Finger selection on console	Finger switch	No significant difference
RF Type	Multipolar/Unipolar	Bipolar/Monopolar	No significant difference
RF Frequency	300kHz – 1 MHz	300kHz – 50 MHz	truSculpt clearance is for up to 50 MHz however actual truSculpt product specifications are identical (300kHz-1 MHz)
Max RF Power	300 W	300 W	Identical
Intensity Adjustment	0-100%	0-100%	Identical
Configuration	Cart mounted console with accessories	Cart mounted console with accessories	Identical
Patient Safety Switch	Yes	Unknown	Subject device has a patient circuit breaker safety switch
Standards Compliance	ISO10993, IEC60601-1 & IEC60601-1-2 Compliant	ISO10993, IEC60601-1 & IEC60601-1-2 Compliant	Identical

Summary of Testing:

The technological characteristics of the Winback Back 3SE System has been verified based on assessments of electrical safety, performance, biocompatibility, software and usability. In addition, an assessment was done to demonstrate that the device effectively raises tissue temperature in a safe and efficient manner.

The following testing has been conducted with satisfactory results:

- Back 3SE Usability & Risk Management: Usability and Risk Management assessments were done using worse-case assumptions to verify user interface, safety features and satisfactory performance.
- Tissue Temperature Elevation Assessment: Studies were done in Korea & France using volunteers of varying skin colors to assess the capacity of the device to elevate tissue temperature in the treatment areas. The smallest and the largest electrodes were tested as well as the facial applicator electrode. Results indicated satisfactory safe therapeutic increases in tissue temperature.
- Biocompatibility: Samples of the tissue contacting probes were tested for cytotoxicity, sensitization and intracutaneous reactivity.
- Software Assessment: Software features were assessed in accordance with FDA software validation guidelines. Levels of Concern, User & System Requirements, Hazard Analysis, Software Requirements, Architectural Design, Software Validation & Testing were all addressed.
- Electromagnetic compatibility: EMC testing was done to evaluate emissions and immunity to electromagnetic fields in accordance with IEC 60601-1-2.
- Electrical safety: Full electrical safety testing was done in compliance with IEC 60601-1.

Conclusion:

The Winback Back 3SE is substantially equivalent to the predicate device. Both devices operate in the same treatment range and voltage and feature intensity adjustments from 0 to 100%. Electrical safety and biocompatibility have been established for both devices.