March 1, 2023

SWIMS America Corp
% Matthieu Commeau
Managing Director
EMERGO, by UL
1133 Westchester Avenue Suite N 220
White Plains, New York 10604

Re: K220014
Trade/Device Name: Rshock
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: January 30, 2023
Received: February 2, 2023

Dear Matthieu Commeau:

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: 2023.03.01 08:24:30 -05'00'

On behalf of
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220014

Device Name
RSHOCK

Indications for Use *(Describe)*
The RSHOCK 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 RSHOCK 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.

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Section 1.5

510(k) Summary

510(k) Summary Pursuant to 21 CFR 807.92

Date: 09/02/2022

1. Submitted By:
   SWIMS America Corp
   1133 Westchester Avenue Suite N 220
   White Plains, NY 10604
   917-371-7388

2. Contact:
   Matthieu COMMEAU
   SWIMS America Corp, Managing Director
   1133 Westchester Avenue Suite N 220
   White Plains, NY 10604
   917-371-7388
   mat@winback.com

3. Product:
   RSHOCK
   (21CFR§878.4400) Class II
   RSHOCK
   Product code PBX

4. Common/Trade Name:
   Massager, Radiofrequency Induced Heat
   RSHOCK

Description:

The RSHOCK device generates 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 resistive monopolar mode.

The product consists of a power console, LCD monitor, and accessories including resistive electrodes. The unit can provide one level of treatment frequency at 300kHz.

Intended Use:

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

Substantial Equivalence/Technological Characteristics:

The RSHOCK device is substantially equivalent to the Back 3SE device from Winback USA Corp which was cleared under premarket notification K162828. Both devices are consoles with electrode accessories capable of operation in monopolar mode of 300kHz radiofrequency.

Both devices operate in the same treatment range and voltage and feature intensity adjustments. 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:** RSHOCK	**Predicate Device:** Winback Back 3SE K162828	**Explanation of Differences**
Regulation and Product Classification Code	21 CFR 878.4400 PBX	21 CFR 878.4400 PBX	None
Indications for Use	The RSHOCK 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 RSHOCK 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. The Winback Back 3SE massage device is intended to provide a temporary reduction in the appearance of cellulite.	Identical
Massaging Hand piece	No	Yes	No significant difference
Electrode Shapes	Square and circular	Square and circular	Identical
Infrared Light	No	No	Identical
Vacuum (suction)	No	No	Identical
Treatment Activation	Finger selection on console	Finger selection on console	Identical
RF Type	Unipolar	Multipolar/Unipolar	No significant difference
RF Frequency	300kHz	300kHz – 1MHz	No significant difference
Max RF Power	100W	300W	No significant difference
Intensity Adjustment	0-3 levels	0-100%	Not the same scale but the same values
Configuration	Console with accessories	Cart mounted console with accessories	No significant difference
Patient Safety Switch	Yes	Yes	Identical

Summary of Testing:

The technological characteristics of the RSHOCK System has been verified based on assessments of electrical safety, performance, biocompatibility, software and usability.

The following testing has been conducted with satisfactory results:

- RSHOCK Usability and Risk Management: Usability and Risk Management assessments were done using worse-case assumptions to verify user interface, safety features and satisfactory performance.
- 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 RSHOCK is substantially equivalent to the predicate device. Both devices operate in the same treatment range and voltage and feature intensity adjustments. Electrical safety and biocompatibility have been established for both devices.