11/1/2022

SWIMS America Corp
% Mr. Matthieu COMMEAU
Managing Director
SWIMS America Corp,
1133 Westchester Avenue Suite N 220
White Plains, New York 10604

Re: K214090
Trade/Device Name: BACK3 COLOR
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: September 30, 2022
Received: October 3, 2022

Dear Mr. 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,

for 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)*
K214090

Device Name
BACK3 COLOR

Indications for Use *(Describe)*
The BACK3 COLOR 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 BACK3 COLOR 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.

510(k) Summary Pursuant to 21 CFR 807.92

Date: 10/31/2022

1.	Submitted By:	SWIMS America Corp 1133 Westchester Avenue Suite N 220 White Plains, NY 10604
2.	Contact Person:	Mr. Matthieu COMMEAU, Managing Director of SWIMS America Corp, 1133 Westchester Avenue Suite N 220 White Plains, NY 10604 Phone: 917-371-7388 Email: mat@winback.com
3.	Common Name:	Winback Back 3SE Massager, Radiofrequency Induced Heat
4.	Trade Name:	BACK3 COLOR
5.	Classification:	Class II
6.	Device Product Code:	PBX

Description:

The BACK3 COLOR 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 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 300kHz to 1MHz.

Intended Use:

The BACK3 COLOR 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 BACK3 COLOR massage device is intended to provide a temporary reduction in the appearance of cellulite.

Substantial Equivalence/Technological Characteristics:

The BACK3 COLOR device is substantially equivalent to the Back 3SE device from Winback USA Corp which was cleared under premarket notification K162828. 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.

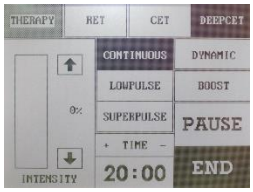
Both devices operate in the same treatment range and voltage and feature intensity adjustments from 0 to 100%. Electrical safety and biocompatibility have been established for both devices. No direct comparison was made since there are no significant differences in operation and test results indicate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

The table below summarizes the equivalence of the devices.

Predicate Device Comparison Table

Element of Comparison	**510(k) Device:** BACK3 COLOR K214090	**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 BACK3 COLOR 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 BACK3 COLOR 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	Yes	Yes	Identical
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	Multipolar/Unipolar	Multipolar/Unipolar	Identical
RF Frequency	300kHz – 1MHz	300kHz – 1MHz	Identical
Max RF Power	300W	300W	Identical
Intensity Adjustment	0-100%	0-100%	Identical
Configuration	Cart mounted console with accessories	Cart mounted console with accessories	Identical
Patient Safety Switch	Yes	Yes	Identical

Accessories provided with the device (diameter of the electrodes-mm)	CET handpiece RET handpiece CET straight CET electrodes (40, 60, 70mm) RET electrodes (40, 60, 70mm) Convex CET electrodes Thai CET Electrode Convex RET Electrode Protect Ring Neutral plate Physio Blade and Connector RET Bracelet Capacitive Fix Pad Resistive Fix Pad Neutral Fix Pad Finger handpiece Flex Pack TECAR 6.0 Handpiece TECAR 6.0 Tip (M) 3-Polar applicator for Body 3-Polar applicator for Face Safety Switch Double Cable Active cable for CET electrodes Active cable for RET electrodes	CET Handpiece RET Handpiece CET electrodes (40, 60, 70mm) RET electrodes (40, 60,70mm) Active cable for CET electrodes Active cable for RET electrodes Neutral plate Safety switch 3-Polar applicator for Body 6- Polar applicator for Body 3- Polar applicator for Face	Addition of some new accessories which does not impact the security and the performance of the subject device. These accessories have been added to facilitate the treatment of the therapist depending on the area to be treated. These accessories have however the same utility, the same intended uses and the associated modes are identical to those of the predicate (CET, RET... etc). The TECAR 6.0 Handpiece and TECAR 6.0 Tip are pieces connected with each other. They are to be used with the fractal RET mode.
Modes	CET RET DEEP RET DEEP CET PULSE FRACTAL FACE 3-POLAR BODY 3-POLAR	CET RET DEEP CET FACE 3-POLAR BODY 3-POLAR BODY 6-POLAR	Addition of some new modes which does not impact the security and the performance of the device. These modes have been added to facilitate the treatment of the therapist depending on the area to be treated. These modes have however the same utility and the same intended uses as those of the predicate (CET, RET, etc). The FRACTAL mode is only compatible with the use of the accessory TECAR 6.0. Its frequency is the same as the RET. This mode has for aim to deliver TECAR energy in fractional form which is divided into several heating points for a focused and targeted deep action.
Functions	MINI MEDIUM BOOST SWAP DYNAMIC	LOWPULSE CONTINUOUS SUPERPULSE NORMAL DYNAMIC BOOST	Addition of some new functions which does not impact the security and the performance of the device. These modes have been added to facilitate the treatment of the therapist depending on the area to be treated. These modes have

			however the same utility and the same intended uses as those of the predicate (CET, RET, etc). Change of name of functions: The name of the functions has been modified. However, the functions are the same as those of the predicate. LOWPULSE function was renamed by MINI. CONTINUOUS was renamed by MEDIUM and SUPERPULSE by BOOST.
Design	**Front view**:  **User Interface**:  	**Front view**:  **User Interface**:  	Aesthetic difference: The user interface design evolved: graphic and color changes.
Size (height x width x depth)- in millimeters	148x306x358	148x306x358	Identical
Weight	5 kg	5 kg	Identical

Summary of Testing:

The technological characteristics of the BACK3 COLOR System has been verified based on assessments of electrical safety, performance, biocompatibility, software and usability.

The following testing has been conducted with satisfactory results:

- BACK3 COLOR 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.
- Human being testing : a tissue temperature elevation study was conduct to demonstrate ability of all applicators of subject device to maintain therapeutic temperature on the surface of the human skin. The study was conduct on three different people on three body parts with all device operation modes and at the lowest and highest power settings. The skin and room temperatures were measured.

Conclusion:

The BACK3 COLOR is substantially equivalent to the predicate device (K162828). 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.