September 14, 2023

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

Re: K230167
Trade/Device Name: BACK 4
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, PBX
Dated: August 17, 2023
Received: August 17, 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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K230167

Device Name
BACK 4

Indications for Use *(Describe)*
The BACK 4 device employs RF technology or EMS technology for the treatment of selected medical conditions.

The BACK 4 device in RF mode 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 BACK 4 massage device is intended to provide a temporary reduction in the appearance of cellulite.

The BACK 4 device in EMS mode is intended for:
*Prevention or retardation of disuse atrophy
*Increasing local blood circulation
*Muscle re-education
*Maintaining or increasing range of motion.

The RF treatment mode and EMS mode should not be used in combination or sequentially.

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.

Section 1.5

510(k) Summary

Date : 09/13/2023

1.	Submitted By:	SWIMS America Corp 1133 Westchester Avenue Suite N 220 White Plains, NY 10604 Tel. 917-371-7388
2.	Contact Person :	Mr. Matthieu COMMEAU Managing Director of SWIMS America Corp 1133 Westchester Avenue Suite N 220 White Plains, NY 10604 Tel. 917-371-7388 Email : mat@winback.com
3.	Common Name:	BACK4 Massager, Radiofrequency Induced Heat therapy and Electrostimulation device
4.	Trade Name :	BACK 4
5.	Regulation Number:	21 CFR 890.5850
6.	Regulation Name:	Powered Muscle Stimulator
7.	Device Product Codes:	IPF, PBX
8.	Regulatory Class:	II
9.	Predicate Devices:	Primary Predicate Device: BACK3 COLOR, K214090 Secondary Predicate Device: Evolve System with the T3 Applicator, K210877

Description:

The BACK 4 device generates high frequency sinusoidal current with a monopolar mode of application using two electrodes. A neutral electrode is placed in contact with the patient and a handheld active 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 capacitive or resistive monopolar modes and a multipolar mode.

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

The product can also employ EMS technology. It generates a 4kHz or 1.5kHz electrostimulation signal (modulated at a frequency set between 2Hz and 200Hz).

The two RF and EMS technologies should not be used in combination or sequentially.

An Emergency stop button feature allows the patient to shut down the unit in the event of any discomfort.

Intended Use:

The BACK 4 device employs RF technology or EMS technology for the treatment of selected medical conditions.

The BACK 4 device in RF mode 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 BACK 4 massage device is intended to provide a temporary reduction in the appearance of cellulite.

The BACK 4 device in EMS mode is intended for:
*Prevention or retardation of disuse atrophy
*Increasing local blood circulation
*Muscle re-education
*Maintaining or increasing range of motion.

The RF treatment mode and EMS mode should not be used in combination or sequentially.

Substantial Equivalence/Technological Characteristics:

The BACK 4 device is substantially equivalent to the following primary and secondary devices for the technology RF and EMS accordingly.

Device	**Manufacturer**	**510(k) No.**	**Technical characteristics similar to the Subject device**
Primary device			
BACK3 COLOR Product codes: PBX	Daeyang Medical	K214090 (SWIMS America Corp)	RF technology (300kHz-1MHz)
Secondary device			
Evolve System with the T3 Applicator Product codes : IPF, PBX, GZJ	InMode Ltd.	K210877	EMS technology signals

- Primary predicate device (RF technology)

The BACK 4 device is substantially equivalent to the BACK3 COLOR device from SWIMS America Corp which was cleared under premarket notification K214090. 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.

- Secondary predicate device (EMS technology)

The BACK 4 device shares also the same intended use and Product codes (PBX, IPF) as the FDA-Cleared Evolve System with the T3 Applicator (K210877). Both devices are also designed to deliver electro-muscle stimulation (EMS) for the treatment of different body areas for various medical

applications. These devices have the same range of frequencies (Subject Device: 2-200 Hz; Secondary Predicate: 3-200 Hz).

Indeed, both devices have specifications in common:

- Main Line Frequency (nominal): 50-60 Hz
- Input Voltage (nominal): 100 – 240 VAC.

Please note that the Subject device does not follow the Product code GZJ, which the secondary predicate does follow. That is why some intended uses linked to this Product Code are not found in the intended use of the Subject device: *Symptomatic relief and management of chronic, intractable pain/ post-surgical acute pain.*

These minor differences in technical specifications should not alter the device safety and effectiveness. Furthermore, the Subject device had underwent the required performance testing and validation testing and demonstrates its conformance with device design requirements and with applicable standards.

The safety features and compliance with safety standards of the subject device are similar to the safety features and compliance with safety standards of the predicate devices. All user-contacting materials were tested for biocompatibility and found to comply with the ISO 10993-1 standard. Furthermore, the design and development phases of the subject device were validated throughout a set of performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 standard, electromagnetic compatibility testing according to IEC 60601-1-2 standard, safety and essential performance of nerve and muscle stimulators testing according to IEC 60601- 2-10 standard.

All in all, these performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the BACK 4 is substantially equivalent to its predicate device and can be sold in the US market.

The table below summarizes the equivalence of the devices.

Predicate Device Comparison Table

Element of Comparison	**510(k) Device:** BACK 4	**Primary Predicate Device:** BACK3 COLOR K214090	**Secondary Predicate Device:** Evolve System with the T3 Applicator K210877	**Explanation of Differences**
Regulation and Product Classification Codes	21 CFR 890.5850 (IPF) 21 CFR 878.4400 (PBX)	21 CFR 878.4400 (PBX)	21 CFR 890.5850 (IPF) 21 CFR 878.4400 (PBX) 21 CFR 882.5890 (GZJ)	The BACK 4 device follows the same Product codes as the two predicate devices: PBX, IPF. However, BACK 4 does not use the code GZJ: Transcutaneous electrical nerve stimulator for pain relief. Therefore, BACK 4 does not have the indications for use of the GZJ Product Code. This does not raise new questions of safety and effectiveness.
Prescription/OTC	Prescription	Prescription	Prescription	Identical
Indications for Use	The BACK 4 device employs RF technology or EMS technology for the treatment of selected medical conditions. **PBX code:** The BACK 4 device in RF mode 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 BACK 4 massage device is intended to provide a temporary reduction in the appearance of cellulite. **IPF code:** The BACK 4 device in EMS mode is intended for: *Prevention or retardation of disuse atrophy *Increasing local blood circulation *Muscle re-education *Maintaining or increasing range of motion.	**PBX code:** 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 Evolve System with the T3 Applicator employs RF technology or EMS-TENS technology for the treatment of selected medical conditions. **PBX code:** The T3 Applicator in RF mode is intended for the temporary relief of minor muscles aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation. **IPF code:** The T3 Applicator in EMS mode is intended for: *Relaxation of muscle spasms *Prevention or retardation of disuse atrophy *Increasing local blood circulation *Muscle re-education *Maintaining or increasing range of motion	The BACK 4 device shares the same intended for use as BACK3 COLOR and Evolve System for the RF technology (PBX code). Also, the BACK 4 device has less indications for use than Evolve System with the T3 Applicator for EMS-TENS modes. Therefore, the BACK 4 device does not have new indications for use compared to the two predicate devices for RF and EMS technologies. This does not raise new questions of safety and effectiveness.

	The RF treatment mode and EMS mode should not be used in combination or sequentially.		*Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. **GZJ code:** The T3 Applicator in TENS mode is intended for: *Symptomatic relief and management of chronic, intractable pain *Post-surgical acute pain *Post-trauma acute pain. The RF treatment mode and EMS/TENS mode should not be used in combination or sequentially.	
Environment Used	Hospital or Clinic setting	Hospital or Clinic setting	Hospital or Clinic setting	Identical
Performance standards (FDA recognized consensus standards)	**IEC 60601-1**: General requirements for basic safety and essential performance **IEC 60601-1-2**: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. **IEC 60601-2-10**: particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle stimulators. **IEC 60601-1-6:** General requirements for basic safety and essential performance -Collateral standard: Usability.	**IEC 60601-1**: General requirements for basic safety and essential performance **IEC 60601-1-2**: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. **IEC 60601-2-10**: particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle stimulators. **IEC 60601-1-6**: General requirements for basic safety and essential performance -Collateral standard: Usability.	**IEC 60601-1**: General requirements for basic safety and essential performance **IEC 60601-1-2**: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. **IEC 60601-2-10**: particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle stimulators. **IEC 60601-1-6:** General requirements for basic safety and essential performance - Collateral standard: Usability.	The BACK 4 device complies to the same performance standards as the two predicate devices, except to IEC 60601-2-2 as the Subject device is not intended to be used in a surgical environment nor in an emergency. Also, the BACK 4 device is not a life supporting device. This does not raise new questions of safety and effectiveness.

			EN IEC 60601-2-2 :Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and high-frequency surgical accessories.	
Applicator Shapes	Square, rectangular and circular	Square, rectangular and circular	Rectangular	Identical to the primary predicate device. Difference in shape compared to the secondary predicate device. However, this difference does not raise any new questions of safety and effectiveness compared to the secondary predicate device. The biocompatibility testing and usability attest of the safety of these accessories.
Infrared Light	No	No	No	Identical
Vacuum (suction)	No	No	No	Identical
Applied energy	RF/EMS	RF	RF/EMS-TENS	The BACK 4 device has the same RF technological characteristics as the primary predicate device. The subject device can apply the same energy EMS as the secondary predicate device. However, the BACK 4 does not use GZJ as the secondary predicate device does. So, the subject device does not have TENS energy. This does not raise new questions of safety and effectiveness.
Power source	Main line frequency (nominal): 50-60Hz. Input Voltage (nominal): 100-240VAC. Input current (rms): 1.25Aac @240Vac and 3Aac @ 100Vac.	Main line frequency (nominal): 50-60Hz. Input Voltage (nominal): 100-240VAC. Input current (rms): 1.25Aac @240Vac and 3Aac @ 100Vac. .	Main line frequency (nominal): 50-60Hz. Input Voltage (nominal): 100-240VAC. Input current (rms): 4A.	Power source characteristics are identical to the primary predicate device. The power source characteristics are different to those of the secondary predicate device. The main line frequency and input voltage are similar, except for the input current. However, this difference does not raise new safety and effectiveness questions as electrical safety testing has been performed following state of the art standards.

RF Type	Multipolar/Unipolar	Multipolar/Unipolar	Multipolar/Unipolar	Identical
RF Frequency	300kHz – 1MHz	300kHz – 1MHz	1MHz	Identical to the Primary predicate device for RF technology. The RF frequency of the secondary device falls within range of the subject device. This difference does not raise any new questions of safety and effectiveness compared to the secondary predicate device.
Maximum RF output Power	300W	300W	75W	Identical to the primary predicate device. Different from the secondary predicate device. However, this difference does not raise new questions of safety and effectiveness. RF output power has already been cleared with the primary predicate device.
Electrical type	Type BF	Type BF	Type BF	Identical
EMS output specifications; waveform	Biphasic with symmetrical waveform	N.A	Symmetrical Biphasic waveform	Identical
EMS Frequency	2 to 200Hz	N.A	3 to 200 Hz	Not identical. The EMS frequency range of the subject device has minor difference to the secondary predicate device. This difference does not raise any new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Patient Leakage Current -Normal Condition (uA)	<50uA patient leakage	N.A	<100uA patient leakage	Not identical. Patient leakage current range has minor difference to the patient leakage current range of the secondary predicate device. This difference does not raise any new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.

Patient Leakage Current-Single Fault condition (uA)	<300uA line leakage	N.A	<300uA line leakage	Identical to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Number of Output channels	3	3	6	Not identical. The BACK 4 device has less output channels than the secondary predicate device. This does not raise new questions of safety and effectiveness.
Console	Console, including a power supply unit, controller, and user interface including a LCD touch screen.	Console, including a power supply unit, controller, and user interface including a LCD touch screen.	Console, including a power supply unit, controller, and user interface including a LCD touch screen.	Identical
Software control	Yes	Yes	Yes	Identical
Indicator Display	On/Off status Voltage/current level	On/Off status Voltage/current level	On/Off status Voltage/current level	Identical
Battery	No	No	No	Identical
Timer Range (minutes)	0-60 (minutes)	0-60 (minutes)	0-60 (minutes)	Identical
Accessories provided with the device (diameter of the electrodes in millimeters)	**TECAR X handset**	/	T3 Applicator: Up to 6 units connected to the console via 6 designed cables and 6 designated connection port. *Size of the applicator : 67.3mm L x 54.3mm D*	Comparison with the primary predicate device: *Addition/deletion of some accessories for the subject device compared to the primary predicate device: additional accessories provided with the subject device are indicated in **blue**. The addition of these accessories does not raise new questions of safety and effectiveness 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 use as the primary predicate device and the associated modes are identical to those of the predicate (CET, RET, …etc.).
	RET Bracelet	RET Bracelet		
	Neutral return plate	Neutral plate		
	Neutral handle	/		
	RET electrodes (40, 60, 70mm) [1]	RET electrodes (40, 60, 70mm)		
	Convex RET electrodes (25, **40**mm) [1]	Convex RET electrode (25mm)		
	CET electrodes (40, 60, 70mm)	CET electrodes (40, 60, 70mm)		
	Convex CET electrodes (35, **40**, 60mm)	Convex CET electrode (35, 60mm)		
	Hi-RET electrode	TECAR 6.0 Handpiece TECAR 6.0 Tip (M)		
	Multipolar electrode S	3-Polar applicator Face		
	Multipolar electrode L	3-Polar applicator Body		

	RET Fixed Pad (120mm*60mm) [1]	Resistive Fix Pad		*Change of some accessory denominations: Some accessories have a new name but stay the same as for the predicate (same design, same intended use, same contact material). Not all the listed accessories of the subject device can be connected as the same time, as there are only 3 channels on the device. It is the same for the primary predicate device. [1] These accessories can be used with the EMS mode. Comparison with the secondary predicate device: The secondary predicate device has more accessories connected during the treatment. It can have up to 6 accessories for RF or EMS technology. Due to this configuration, it is less risky for the patient to be treated with less pieces. The difference doesn't raise new questions of safety and effectiveness. The size of the subject device electrodes used for EMS mode is different from the size of the secondary predicate device applicator. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device.
	Neutral Fixed Pad	Neutral Fix Pad		
	TECAR mobile handle	/		
	Neutral generic cable	/		
	RET/CET generic cable	Active cable for CET electrodes Active cable for RET electrodes		
	RET snap cable	/		
	CET Extender	/		
	RET Extender	/		
	Emergency stop button	Safety Switch		
	Power cord	Alimentation cable		
	Essential conductive Cream	/		
	Fascia Blade	Physio Blade and Connector		
	/	CET handpiece		
	/	RET handpiece		
	/	Thai CET Electrode (70mm)		
	/	Protect Ring (50, 70, 80mm)		
	/	Capacitive Fix Pad		
	/	Flex Pack		
	/	Finger Handpiece		
	/	Double Cable		
	/	CET straight		
	/	Flex Pack		
Modes	CET SOFT	CET	RF	Comparison with the primary predicate device: Change of some Mode's names: some modes have a new name but are the same (same intended use and frequencies).
	CET DEEP	CET DEEP		

	RET	RET		This difference does not raise new questions of safety and effectiveness. The Hi-EMS mode does not apply to the primary predicate device. Comparison with the secondary predicate device: Both have the EMS mode. The only difference is the marketing name of it. Electrical safety and EMC testing have been performed for the subject device. This difference does not raise new questions of safety and effectiveness.
	RET + Hi-TENS	DEEP RET		
	Hi-TENS	PULSE		
	MIX	FOCUS 3-POLAR BODY 3-POLAR		
	/	FRACTAL		
	Hi-EMS	/	EMS	
Functions	LOW	MINI	N.A	The names of the functions are the same as those of the primary predicate device, except for LOW function; The MINI function was renamed by LOW. However, the technical characteristics of that LOW function are identical to those of the MINI function.
	MEDIUM	MEDIUM		
	BOOST	BOOST		
	DYNAMIC	DYNAMIC		
	SWAP	SWAP		
	STATIC	STATIC		
Design	The BACK 4 device consists of an AC/DC power supply unit, controller, 2 RF generators and user interface including an LCD touch screen. The delivery of the RF/electrical energy is controlled by a On/Off button positioned on the front panel. The system supports the following components: • LCD display touch screen • Audio loudspeaker • 100-240 VAC power supply • Controller (GMU card) • 2 RF generators The system operates while connected to the accessories (electrodes) in RF mode or in EMS mode.	The BACK3 COLOR consists of an AC/DC power supply unit, controller, 2 RF generators and user interface including an LCD touch screen. The delivery of the RF is controlled by a On/Off button positioned on the front panel. The system supports the following components: • LCD display touch screen • Audio loudspeaker • 100-240 VAC power supply • Controller • 2 RF generators	The EVOLVE system with T3 Applicator consists of an AC/DC power supply unit, controller, 2 RF generators and user interface including an LCD touch screen. The delivery of the RF/electrical energy is controlled by a Start/Stop button positioned on the front panel. The system supports the following components: • LCD display touch screen • Audio loudspeaker • 100-240V • Controller • 2 RF generators	The subject device does not have the same dimensions and design than thee predicate devices. However, the screen of the BACK 4 device has the same size as the cleared device BACK 3 COLOR. Finger selection on screen for the three devices. However, the difference doesn't raise new questions of safety and effectiveness.

		The system operates while connected to the accessories (electrodes) in RF mode.	The system operates while connected to the applicators in RF mode or in EMS-TENS mode.	
Dimension console (height x width x depth) in millimeters	403.6x379.0x190.5	148x306x358	100x460x460	Not identical. However, the difference doesn't raise new questions of safety and effectiveness. The devices are not supposed to be moved.
Weight (kg)	6 kg	5 kg	33 kg	Not identical. The subject device is less heavy than the predicate devices. That difference does not generate a safety and effectiveness issue.
Target temperatures	38-42°C	38-42°C	NA	Identical to the primary predicate device.
Treatment areas	All body, external part except eyes, mouth, heart, mucosa parts and brain area	All body, external part except eyes, mouth, heart, mucosa parts and brain area	Body parts requiring treatment as specified in the indication for use	Identical
Safety features	Emergency stop button	Emergency stop button	System in STOP state level at 60 minutes.	Identical
Sterility	N.A	N.A	N.A	N.A
EMS Output Mode				
Waveform	Biphasic with symmetrical waveform	N.A	Symmetrical Biphasic waveform	Identical
Shape	Sinusoidal	N.A	Rectangular	Not identical. The subject device and the secondary predicate device are capable of muscle stimulation. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new question of safety and effectiveness.

				This characteristic does not apply to the primary predicate device.
Maximum Output Voltage (Vpeak) (+/-10%)	21.8 V @ 500 Ω 32.3 V @ 2 k Ω 36.6 V @ 10 k Ω	N.A	30 V @ 500 Ω 54 V @ 2 k Ω 54 V @ 10 k Ω	Not identical. The subject device provides a lower maximum output voltage than the secondary predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Maximum Output Current (mA) (+/- 10%)	43.6 mA @ 500 Ω 16.2 mA @ 2 k Ω 3.7 mA @ 10 k Ω	N.A	60 mA@ 500 Ω 27 mA @ 2 k Ω 5.4 mA @ 10 k Ω	Not identical. The subject device provides a lower maximum output current than the secondary predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.

Pulse Width (µsec)	Radial mode: 250µsec Focal mode : 250µsec	N.A	20 to 400µsec	Not identical. Radial mode: The pulse width of the subject device is within the range of the pulse width of the secondary predicate device. This difference does not raise any new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device. Focal mode: The pulse width of the subject device is within the range of the pulse width of the secondary predicate device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Frequency (Hz)	2 to 200Hz	N.A	3 to 200 Hz	Not identical. The EMS frequency range of the subject device has minor difference to the secondary predicate device. This difference does not raise any new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Net Charge @ 500 ohms (microC/pulse)	0	N.A	0	Identical to the secondary predicate device. This characteristic does not apply to the primary predicate device.

Maximum Phase Charge (microC)	28.8 microC @ 500 Ω	N.A	24 microC @ 500 Ω	Not identical. The subject device provides a higher maximum phase charge than the secondary predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Maximum Current Density (RMS), (mA/cm^2) (Using smallest electrode conductive surface area)	1.6 (mA/cm^2) Surface = 12.6cm^2	N.A	0.74 (mA/cm^2) Surface = 6.46cm^2	Not identical. The subject device provides a higher maximum current density than the secondary predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.

Maximum Power Density, (mW/cm²) (Using smallest electrode conductive surface area)	15.7 (mW/cm²)	N.A	22.2 (mW/cm²)	Not identical. The subject device provides a lower maximum power density than the secondary predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device. Moreover, the maximum power density is under the limit according to Section 3 of Attachment II (Output Waveforms) of FDA's Powered Muscle Stimulator Guidance (https://www.fda.gov/media/71804/download).

Burst Mode (i.e., pulse trains) **a. Pulses per burst** **b. Bursts per second** **c. Burst duration (seconds)** **d. Duty Cycle [Line (b) x Line (c)]**	Yes, a. 2-200 b. 1 c. 5 sec d. Time on/off	N.A	Yes, a. 3-200 b. 1 c. 1-60 sec d. Time on/off	Not identical. Pulses per burst: The subject device has minor difference in pulses per bust range compared to the secondary predicate device. This difference does not raise any additional questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device. Burst duration: The subject device has a different burst duration than the secondary predicate device. However, the burst duration of the subject device does not fall outside of the burst duration scope of the secondary predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Usability and risk analysis have also been performed to support proof of safety and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device. Moreover, according to Section 3 of Attachment II (Output Waveforms) of FDA's Powered Muscle Stimulator Guidance, for effectiveness in achieving repeated muscle contractions, powered muscle stimulators typically are capable of stimulating muscle for at least one second per burst, and are capable of providing at least one second of muscle relaxation between successive pulse bursts. Regarding the burst characteristics, our subject device provides a muscle stimulation for 5 seconds per burst and a muscle relaxation for 1 second between successive pulse bursts.

ON Time (seconds)	5 sec (6 sec period)	N.A	1-60 sec	Not identical. The subject device does not fall outside of the range of the secondary predicate device. This difference does not raise new question of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
OFF Time (seconds)	1 sec (6 sec period)	N.A	1-60 sec	Not identical. The subject device does not fall outside of the range of the secondary predicate device. This difference does not raise new question of safety and effectiveness compared to the secondary predicate device. This characteristic does not apply to the primary predicate device.
Treatment time (minutes)	Up to 60 minutes	N.A	Up to 60 minutes	Identical

Summary of Testing:

The technological characteristics of the BACK 4 System has been verified based on assessments of electrical safety, performance, biocompatibility, software and usability.

The following testing has been conducted with satisfactory results:

- BACK4 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 conducted to demonstrate ability of all applicators of the RF mode 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:

Based on the comparison to the predicate devices and on the non-clinical performance testing results demonstrating that the BACK 4 is as safe and effective as the primary and secondary predicate devices, the BACK3 COLOR FDA cleared under 510(k) K214090, and the Evolve System with the T3 Applicator cleared under 510(k) K210877 and therefore the subject device is substantially equivalent to these predicate devices.