May 24, 2023

Regenesis Biomedical Inc.
Randy Chavez
VP Regulatory Affairs & Quality Assurance
5301 N Pima Road, Ste 150
Scottsdale, Arizona 85250

Re: K223620
Trade/Device Name: Reprieve by Regenesis™
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: May 23, 2023
Received: May 23, 2023

Dear Randy Chavez:

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
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)*
K223620

Device Name
Reprieve by Regenesis™

Indications for Use *(Describe)*
The Reprieve by Regenesis™ device is indicated to generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.

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.

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510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.
Submitter	Regenesis Biomedical, Inc.
Contact Person	Randy Chavez 5301 North Pima Road Scottsdale, AZ 85250 USA Email: Randy.Chavez@regenesisbio.com Mobile: 480-297-5800 Fax: 866-857-8792
Date Prepared	May 23, 2023
Product Name	Reprieve by Regenesis™
Common Name	Shortwave Diathermy
Device Classification	Class II
Product Code	IMJ
Predicate Devices	Predicate device: • ViaTherm BOOST Diathermy System (K173300). Reference devices: • ThermoPro (K161862) • Intelect SWD100 (K083433) No secondary predicate devices were used in this submission.
Device Description	The Reprieve by Regenesis™ device (Reprieve) is a prescription shortwave diathermy (SWD) device consisting of a single base unit connected to one or two treatment applicators. The device connects to A/C power through an external, off-the-shelf, power supply generating radiofrequency energy which delivers SWD through the treatment applicator(s). The base unit houses an LCD screen with four raised buttons, two on each side of the LCD screen, and an LED light bar. The back of the base unit has a molded slot to accommodate the treatment applicator(s), a pouch to store the power supply, and a cable wrapping loop to organize the treatment applicator cables. The bottom of the base unit has an opening to connect the A/C power supply. The treatment applicator(s) deliver the SWD RF energy and are connected to the base unit with

	factory-affixed coaxial cables. The top is the treatment side of the applicator is a darker color to distinguish it from the lighter-colored bottom, the non-treatment side. The top also has circular imagery denoting the center of the applicator. The Reprieve device generates a 27.12 MHz RF signal that has a 100% duty cycle when programmed to continuous wave (CW) mode. When prescribed for pulsed wave (PW) mode, the pulse rate (e.g., pulses per second) can be varied from 200Hz to 1000Hz in 200Hz increments, and the pulse width (e.g., the elapsed time the pulse is on) from 20µsec to 100µsec in 20µsec increments.
Indications for Use	The Reprieve by Regenesis™ device is indicated to generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.

Comparison of Technological Characteristics with Predicate Device

The table below lists and compares the technological characteristics of the Reprieve by Regenesis™ device and the predicate device, the ViaTherm BOOST Diathermy System.

Attribute	ViaTherm BOOST Diathermy System	Regenesis Biomedical Inc. Reprieve by Regenesis™	Comment
Intended Use/Indication For Use	To generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.	To generate deep heating within body tissues for the treatment of conditions such as relief of pain and muscle spasms.	Same as predicate
Trade/Device Name	BOOST Diathermy System	Reprieve by Regenesis™	---
510(k) Number	K173300	K223620	---
Class	II	II	Same as predicate
Product Code	IMJ	IMJ	Same as predicate
Regulation Number	21 CFR 890.5290	21 CFR 890.5290	Same as predicate
Regulation Name	Shortwave Diathermy Device	Shortwave Diathermy Device	Same as predicate
Target Population	Adults (not to be used on children) whose medical conditions would be treated, in whole or in part, with therapeutic warmth. Some examples of these types of medical conditions are as follows: pain and swelling in soft tissue injuries; muscle spasms or pain due to injury or overtraining.	Adults (not to be used on children) whose medical conditions would be treated, in whole or in part, with therapeutic warmth. Some examples of these types of medical conditions are as follows: pain and swelling in soft tissue injuries; muscle spasms or pain due to injury or overtraining.	Same as predicate

Attribute	ViaTherm BOOST Diathermy System	Regenesis Biomedical Inc. Reprieve by Regenesis™	Comment
Intended Environment for Use	OTC device intended for use by patients in non-clinical environments, including the home.	Prescription device designed for home use by a nontechnical operator with or without the immediate supervision of a healthcare practitioner.	Prescription use versus OTC does not raise issues of safety or effectiveness
Design	User-friendly device designed with safety mechanisms that enable it to be effectively and safely operated by a nontechnical adult in non-clinical environments, including the home setting.	User-friendly device designed with safety mechanisms that enable it to be effectively and safely operated by a nontechnical adult in a non-clinical setting.	Same as predicate
Mechanism of Action	Deep heating of tissue by therapeutic application of radio frequency electrical currents.	Deep heating of tissue by therapeutic application of radio frequency electrical currents.	Same as predicate
Anatomical Site Locations	Multi-use therapy garments for target location areas of 5 to 18 square inches: Arm (e.g., bicep, wrist, forearm), back, shoulder, leg (e.g., thigh, knee, calf), foot	Multi-purpose treatment applicator pad(s) usable on all typical target locations, up to 28 square inches: Arm (e.g., bicep, wrist, forearm), back, shoulder, leg (e.g., thigh, knee, calf), foot	Treatment applicators are designed for use on similar body locations, differences do not raise issues of safety or effectiveness
Treatment time	40-45 minutes	35-45 minutes	Similar treatment times, differences do not raise issues of safety or effectiveness
Available warming control	Single setting as directed by patient.	Single setting as directed by clinician.	Both devices have single setting for use, does not raise issues of safety or effectiveness
Thermal performance	Achieves 4°C temperature rise at 25 minutes.	Achieves 4°C temperature rise at 25 minutes.	Same as predicate

Attribute	ViaTherm BOOST Diathermy System	Regenesis Biomedical Inc. Reprieve by Regenesis™	Comment
Materials	Generator Therapy Garment Material • Futuro™ 3M, composed of polyurethane foam, nylon, polyester, polyethylene, and spandex • Velcro Extender Strap Charger Cord Patient Interface – 100% cotton	Generator – Polycarbonate/ABS Treatment Applicator Pad Material • Polycarbonate Makrolon™ 2458 Treatment Applicator Cable – polyvinyl chloride (PVC) Patient Interface – Autoflex EB (polyester film)	Both devices utilize materials that are biocompatible for the intended use based on the nature and duration of contact which does not raise issues of safety or effectiveness
Safety factors	The device treatment is intended to be self-administered in the home. The device is battery operated. It contains circuit boards that determine if the garment is making sufficient contact with the user, and if so, will output the designated power. The treatment time is based on the life of the battery, preventing the user from over treating.	The device treatment is intended to be self-administered in the home. The device is connected to an external power supply. It contains circuit boards that determine if the device is delivering sufficient power based on contact with the user, and if required, will increase or decrease the needed output power within a 10W limitation. The treatment time is preset to 30 minutes, preventing the user from over treating.	Both devices are intended to be self-administered at home with power control based on applicator contact with patient and time limited. The differences to not raise issues of safety or effectiveness
Biocompatibility	Established	Established to ISO 10993-1:2018	Same as predicate

Attribute	ViaTherm BOOST Diathermy System	Regenesis Biomedical Inc. Reprieve by Regenesis™	Comment
Operating Frequency	Radiofrequency as defined per 21 CFR 890.5290: 13.56 MHz	Radiofrequency as defined per 21 CFR 890.5290: 27.12 MHz	Both devices use the radiofrequency spectrum as defined by regulatory statute and safety standards, the difference does not raise issues of safety or effectiveness
RF Power	5W	<10W	Both devices use less than 10W of power and can be classified as low power devices per IEC 60601-2-3. As both devices use less than 10W of power, the difference does not raise issues of safety or effectiveness
RF Connector	BNC (patient accessible)	SMA (not patient accessible)	Both connectors provide RF connection, but have different threading; the difference does not raise issues of safety or effectiveness
Impedance	50 Ohms nominal	50 Ohms nominal	Same as predicate
Power Supply	Ni-MH AA – 1.2V x4 (4.8V), 2000 mAh	DC power provided by an external A/C to D/C power supply (40W, medical grade Class II wall plug)	Both devices use DC power to deliver RF energy, the difference does not raise issues of safety or effectiveness

Attribute	ViaTherm BOOST Diathermy System	Regenesis Biomedical Inc. Reprieve by Regenesis™	Comment
Duty Cycle	Continuous Wave (100%)	Continuous Wave (100%) Pulsed Wave (Varies due to pulse parameters. These parameters are selected by the clinician and can range from 20-100µ pulse width and 200-1000Hz pulse rate, resulting in a range of duty cycles from 0.4 to 10.0%)	Both devices have a continuous wave mode. The pulsed wave mode can be selected by the ordering clinician. The addition of pulsed wave modes for a prescription shortwave diathermy device that range in power from 0.3 to 7.0 W of power, similar to the 5.0 W of power of the predicate device, and settings similar to the reference predicate devices does not raise issues of safety or effectiveness
Load Standing Wave Ratio (LSWR)	3.0:1 max	1.5:1 max	Improved LSWR allows for more efficient RF delivery over a wide variety of body loads, therefore the difference does not raise issues of safety or effectiveness
Weight (base unit)	1.6 lbs.	5.0 lbs.	Both devices are lightweight, the difference does not raise issues of safety or effectiveness

Attribute	ViaTherm BOOST Diathermy System	Regenesis Biomedical Inc. Reprieve by Regenesis™	Comment
Size (base unit)	2.25” x 4.875” x 6.5”	6.1” x 11.3” x 11.4”	Larger size allows for LCD screen and applicator storage, the difference does not raise issues of safety or effectiveness
Sterility	Non-sterile	Non-sterile	Same as predicate
Operating Temperatures	59 to 104 °F (15 to 40 °C) at relative humidity of 30%-90% (noncondensing) and pressure of 700-1060 hPa.	41 to 104 °F (5 to 40 °C) at relative humidity of 15%-90% (noncondensing) and pressure of 700-1060 hPa.	Similar operating temperatures, the difference does not raise issues for safety or effectiveness
Storage Temperatures	50 to 140 °F (10 to 60 °C) at relative humidity of 15%-90% (noncondensing) and pressure of 700-1060 hPa.	-13 to 158 °F (-25 to 70 °C) at relative humidity of 15%-90% (noncondensing) and pressure of 700-1060 hPa.	Wider storage temperature range, the difference does not raise issues of safety or effectiveness
Coil design	Two flat spiral coils embedded in a fabric garment applicator	Single flat spiral coil embedded in a polycarbonate applicator	Both devices use spiral coils to generate RF field, the difference does not raise issues of safety or effectiveness
Radiation Safety	Established	Established	Same as predicate
RF Shielding	Yes	Yes	Same as predicate
Designed to meet Electrical Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60606-1-6 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60606-1-6 IEC 60601-1-11 IEC 60601-2-3	Additional safety standard that is specific to shortwave medical devices does not raise issues of safety or effectiveness

Performance Data	The following performance data were provided in support of the substantial equivalence determination. **Electrical Safety and electromagnetic compatibility (EMC)** Electrical safety and EMC testing was conducted on the Reprieve device and complies with the following standards: • IEC 60601-1: General requirements for basic safety and essential performance • IEC 60601-2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment • IEC 60601-1-2: Collateral Standard: Electromagnetic disturbances - Requirements and tests • IEC 60601-1-6: Collateral standard: Usability • IEC 60601-1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment • IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices **Usability/Human Factors** A validation study was completed to evaluate the usability/human factors of the Reprieve device and the associated labeling. The representative naïve users completed simulated-use tasks and answered knowledge comprehension questions to evaluate the usability of the Reprieve device for critical tasks applicable in a home-use environment. The results of the usability validation study were positive and demonstrated that mitigations addressing use-related risks made during Reprieve device design and development were effective. Usability and Human Factors testing was conducted on the Reprieve device and complies with the FDA guidance document Applying Human Factors and Usability Engineering to Medical Devices issued February 3, 2016. **Biocompatibility** Reprieve meets the requirements of ISO 10993-1:2018, ISO 14971:2019, and FDA General Guidance on the Use of International Standard ISO 10993-1, dated September 4, 2020; for a surface device that has long-term (>30 days) contact with intact skin and can be considered safe for use as intended. **Software Verification and Validation Testing** Software verification and validation testing was conducted on the Reprieve device. Documentation was provided as recommended by the following FDA guidance documents:

	• Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. May 11, 2005 • Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Guidance for Industry and Food and Drug Administration Staff. October 2, 2014 The documents submitted demonstrate compliance with IEC 62304: Medical device software – Software life cycle processes. The software for this device was considered a "moderate" level of concern as, prior to mitigation of hazards, a failure of the software could result in minor injury to a user of the device. **Bench Testing** The Reprieve by Regenesis™ device demonstrated through temperature testing in an in vitro muscle phantom therapeutic deep heating between 40-45°C at a 1-2cm depth from the surface of the treatment applicator for 15-20 minutes. This testing was also evaluated at the surface and at a 3cm depth to assure that intramuscular tissue temperature from the surface to 3cm did not exceed 45°C.
Conclusions	The Reprieve by Regenesis™ (Reprieve) device is as safe and effective as the predicate shortwave diathermy (SWD) device. The Reprieve device has the same intended uses and indications, similar technological characteristics, and principles of operation as the predicate device. The results of bench testing demonstrate a similar increase of 4°C at 1cm depth for both the Reprieve device and the predicate device. Both use radiofrequency energy as defined per 21 CFR 890.5290, either 13.56 MHz or 27.12 MHz. The Reprieve device is indicated for prescription use and has additional SWD technological features with pulsed SWD options similar to the reference SWD devices. There are no additional claims associated with the additional SWD technological features. Usability validation testing demonstrated the Reprieve device can be used safely and effectively in the intended home-use patient population. The Reprieve device is compliant to the same safety standards as the predicate device, demonstrating the safe design of the Reprieve device. The technological differences raise no issues of safety or effectiveness. Therefore, the Reprieve by Regenesis™ device is substantially equivalent to the predicate device.