August 29, 2025

Trinity Medical Solutions
℅ Jamie Owsiany
Official Correspondent
Hoy and Associates Regulatory Consulting
1830 Bonnie Way
Sacramento, California 95825

Re: K251026
Trade/Device Name: Regenesis EMS Chair
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: Class II
Product Code: KPI
Dated: July 31, 2025
Received: August 1, 2025

Dear Jamie Owsiany:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica K. Nguyen -S

Jessica Nguyen
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K251026

Device Name
ReGenesis EMS Chair

Indications for Use *(Describe)*
The ReGenesis EMS Chair is intended to provide non-invasive electromagnetic stimulation to a weak pelvic floor muscle for the purpose of rehabilitation. The procedure is intended to strengthen the pelvic floor muscle and restore the neuromuscular control for the treatment of urinary incontinence in both male and female patients.

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

1. Submitter Information

510 (k) submitter:	Trinity Medical Solutions
Address:	105 Citation Court Homewood, AL 35209
Applicant Contact Person:	Mr. Mark Rohrer Phone: 205-356-1172 Email: Mrohrer0603@gmail.com
Correspondent Contact:	Mrs. Jamie Carlton Phone: 706-399-1304 Email: jamieowsiany@hoyregulatory.com
Preparation date:	August 29, 2025

2. Device Name

Trade Name of the Device:	ReGenesis EMS Chair
Common Name:	Nonimplanted electrical continence device
Classification Name:	Stimulator, Electrical, Non-Implantable, For Incontinence
Classification Regulation:	21 CFR 876.5320
Device Class:	II
Panel:	Gastroenterology/Urology
Product Code:	KPI

3. Predicate Device

	510(k) Number	Trade Name of the Device
Predicate:	K181497	HPM-6000UF

The predicate device was never subjected to a design related recall.

4. Device Description

The ReGenesis Chair is an electromagnetic muscle stimulation device. It is intended to provide non-invasive electromagnetic stimulation to a weak pelvic floor muscle for the purpose of rehabilitation. The procedure is intended to strengthen the pelvic floor muscle and restore the neuromuscular control for the treatment of urinary incontinence in both adult male and female patients. This is intended to be operated by trained professionals only.

The ReGenesis EMS Chair consists of the main unit (the chair) and a wired, color, touch screen, control Panel. The device consists of a control unit that internally houses a power supply, cooling system, user interface, and control system. The electromagnetic coil is contained in the chair applicator, which is fashioned as a seat for the patient. The subject device uses electromagnetic fields to stimulate the muscles of the pelvic floor.

5. Indications For Use

The ReGenesis EMS Chair is intended to provide non-invasive electromagnetic stimulation to a weak pelvic floor muscle for the purpose of rehabilitation. The procedure is intended to strengthen the pelvic floor muscle and restore the neuromuscular control for the treatment of urinary incontinence in both male and female patients.

6. Comparison of the Technological Characteristics with Predicate Device

Device & Predicate Device(s):	K251026 (Subject)	K181497 (Predicate)
Device Name	ReGenesis EMS Chair	BTL HPM-6000U
Indication for use	The ReGenesis EMS Chair is intended to provide non-invasive electromagnetic stimulation to a weak pelvic floor muscle for the purpose of rehabilitation. The procedure is intended to strengthen the pelvic floor muscle and restore the neuromuscular control for the treatment of urinary incontinence in both male and female patients.	HPM-6000UF is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.
Function	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation
Type of energy	Magnetic field	Magnetic field
Power source	AC110 - 120V, 50/60Hz, 12A	100-240 V AC, 50-60 Hz, max 14 A
Therapy Process	Specific therapy parameters are selected by the clinician based on the patient's symptoms.	Specific therapy mode is selected by the clinician based on the patient's symptoms.
Pulse shape	Rectangular biphasic	Sine, biphasic
Therapy modes	Single continuous manual mode	Single continuous manual mode
Applicator	Chair	Chair
Stimulation source	Magnetic coil	Magnetic coil
Magnetic field strength	2T±20%	0.7-2.5 T
Pulse width	310μs (±20μs)	280 μs (±20%)
Pulse repetition rate	1-50 Hz	1-150 Hz
Applicator dimensions (WxHxD)	27x24x27 in.	29x29x29 in.
Variation of Pulse intensity (dB/dt)	Up to 24 mT/ μs±20%	Up to 28 mT/ μs±20%

Pulse amplitude adjustment	0-100%	0-100%
Therapy time / regimen	0-30 mins; separated by at least 2 days	0-60 min session (recommend 30 min); separated by at least 2 days
Interface	Touch screen	Touch screen
Firmware controlled	Yes	Yes
Treatment Environment	Hospital/Clinics only	Hospital/Clinics only

As evidenced by the above table, both the subject and the predicate devices have similar intended use, but the subject and predicate devices have different technological characteristics. However, the differences in technological characteristics between the subject and the predicate do not raise different questions of safety or effectiveness. Performance testing was conducted on the subject device to demonstrate substantial equivalence to the predicate device.

7. Non-Clinical Testing

Below is a list of the tests that were performed and successfully completed for the subject device per the below guidance and standards:

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance*
- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*
- IEC 60601-2-10:2016 – *Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*
- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

Additionally, performance bench data was submitted for device performance and durability of the subject device. This data included:

- Service life verification test
- Stimulation Coil Surface Temperature Rise Test

All pre-determined acceptance criteria were met.

8. Conclusions

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.