November 14, 2024

Shenzhen Xinrun Electric Appliances Co Ltd
℅ Tulin Li
Medical Device Consultant
Huide Medical Technology Service Group Co., Ltd
Room 703, Building 16, South Bank Plaza, Exhibition Bay,
Zhancheng Community, Fuhai Street, Bao'an District
Shenzhen, Guangdong 518053
China

Re: K242940
Trade/Device Name: Xrecovery (XR-001)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: September 10, 2024
Received: September 25, 2024

Dear Tulin Li:

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242940

Device Name
Xrecovery (XR-001)

Indications for Use *(Describe)*
The Xrecovery is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.

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.

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"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
-K242940

1. Submitter of 510(K):

Sponsor:

Company Name:	SHENZHEN XINRUN ELECTRIC APPLIANCES CO LTD
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Application Correspondent:

Company Name:	Huide Medical Technology Service Group Co., Ltd
Address:	Room 703, Building 16, South Bank Plaza, Exhibition Bay, Zhancheng Community, Fuhai Street,Shenzhen,Guangdong,518053,China
Contact person:	Mr. Tulin Li
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Date 510(k) Summary Prepared: November 2,2024

2. Proposed Device and code:

Device Name	Xrecovery
Model	XR-001
Common Name	Powered Inflatable Tube Massager
Regulation Name	Powered Inflatable Tube Massager
Regulation Number	21 890.5650
Regulatory Class	Class II
Product Code	IRP, ILO

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K183702	Polar Care Wave	Breg Inc.

The predicate device has not been subject to a design-related recall.

4. Device Description:

The Xrecovery is an AC powered, software controlled, multimodality system. The device is intended for application of external cold therapy and intermittent pneumatic compression therapy to be used by, or on the order of, licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings. The device features a multi-setting cold therapy module and multi-setting compression therapy module which can be run simultaneously or independently.

The device contains three key parts: A cold-compression pad with connector, an insulated container to hold ice and water, and a lid that contains a water pump and air pump, electronics to control the pumps, tubing, and an intuitive keypad to operate the device.

The device is intended to be used with Cold-Compression pads only, which are designed for specific application sites. The cold-compression pads are available for the core regions; back, shoulder, hip, and knee and for the extremity region, foot/ankle. The cold-compression pads are connected to the lid tubing and are applied to the body to deliver cold and intermittent compression therapy. The cold compression pads are made of flexible materials that form two bladders. The dual- bladder design allows cold water to continuously flow through one of the bladders to provide cold therapy, and air to be cyclically pumped into and released from a second bladder to provide intermittent pneumatic compression therapy.

The insulated container is filled with ice and water by the user. The water circulates through the cold- compression pad to deliver cold therapy to the application site.

The lid which houses the electronics, water pump, and air pump, is sealed and not accessible by the user. The lid also houses the keypad, which controls the device and allows the user to select the therapies as directed by a healthcare professional

5. Indications for Use

The Xrecovery is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.

6. Comparison of Intended Use and Technological Characteristics

The following table compares the subject device to the predicate device with respect to the indications for use and technological characteristics:

	Primary Predicate Device	Subject Device	Equivalence
Feature	Polar Care Wave (K183702)	Xrecovery(K242940)	/
Product Code Regulation Number	IRP Powered inflatable tube massager (21 CFR 820.5650) ILO Water circulating hot or cold pack (21 CFR 890.5720)	IRP Powered inflatable tube massager (21 CFR 820.5650) ILO Water circulating hot or cold pack (21 CFR 890.5720)	SE
Regulatory Class	II	II	SE
Intended Use	The Polar Care Wave system is intended to treat post-surgical and acute injuries to help reduce edema, swelling, and pain where cold and compression are indicated. It is	The Xrecovery is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is	SE

	intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	
Indications for Use	The Polar Care Wave System is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	The Xrecovery is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	SE
Intended Users	Health Care Professionals and lay users (under prescription).	Health Care Professionals and lay users (under prescription).	SE
Intended Use Environment	Intended for indoor use	Intended for indoor use	SE
Therapy	Cold and Compression Work together or independently	Cold and Compression Work together or independently	SE
Therapy sessions	Manual mode – allows the user to adjust cold and compression settings as directed by a Health Care Professional.	Manual mode – allows the user to adjust cold and compression settings as directed by a Health Care Professional.	SE
Types of Pads	Various anatomical pads: Knee, Shoulder, Back, Hip, Universal, Foot/Ankle	Various anatomical pads: Knee, Shoulder, Back, Hip, Universal, Foot/Ankle	SE
Compression Setting	Available in two levels Low (0-25 mm Hg) Regular (0-50 mm Hg)	Available in two levels Low (0-25 mm Hg) Regular (0-52 mm Hg)	SE
Cold Therapy	Available without and with compression (Low and Regular)	Available without and with compression (Low and Regular)	SE
Therapy Temperature Range	45°F-60°F	45°F-60°F	SE
Heat Therapy	Not Available	Not Available	SE
User Interface	Keypad with indicator lights	Keypad with indicator lights	SE
Operating Fluid	Tap Water	Tap Water	SE
Water Cooling Source	Ice	Ice	SE
Single User Cold Compression Pad	Yes	Yes	SE
Cold Compression Pad Sterility	Non-Sterile	Non-Sterile	SE
Line Voltage / Frequency	100-240 VAC 50/60 HZ	100-240 VAC 50/60 HZ	SE

Substantial Equivalence

None of the performance or technological differences between the Xrecovery and the predicates raise any new issues of safety and effectiveness.

7. Non-Clinical PERFORMANCE DATA

The testing for Xrecovery included use life testing, software, electrical safety, electromagnetic compatibility, biocompatibility and bench testing. Xrecovery passed all testing in support of the substantial equivalence determination:

7.1. Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".” As dictated by the nature of body contact (intact skin) and contact duration (less than 24 hours), the following endpoints were evaluated for the patient-contacting components:

1) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

2) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

3) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

The results of these test demonstrated that the patient-contacting components of the subject device are non-cytotoxic, non-sensitizing, and non-irritating.

7.2. Electrical safety and electromagnetic compatibility

The subject device has been tested in accordance with and found to comply with the following standards:

1) IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

3) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

7.3. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “Moderate” level of concern.

7.4. Performance Testing

The Xrecovery has been subjected to design verification and validation testing. These tests verified and validated the proper operation of the system. The Xrecovery device has been found to be adequately safe and effective for the intended users, its intended uses, and use environment. The labeling materials have been found to be easy to use and understandable to the intended users.

8. Conclusions:

The results of the testing described above demonstrate that the Xrecovery is as safe and effective as the predicate device and supports a determination of substantial equivalence.