January 19, 2024

Chengdu Cryo-Push Medical Technology Co.,Ltd
% Liz Li
Counselor
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K230524
Trade/Device Name: Cold Compression Wrap Pro
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IME
Dated: October 31, 2023
Received: November 20, 2023

Dear Liz 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.

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 Rehabilitation 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)*
K230524

Device Name
Cold Compression Wrap Pro

Indications for Use *(Describe)*
The Cold Compression Wrap Pro is indicated for the temporary relief of minor muscle aches and pains.
The device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneading and stroking of tissues using an inflatable wrap.
The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

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.

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510(k) Summary

K230524

1. Contact Details

1.1 Applicant information

510(k) owner's name	Chengdu Cryo-Push Medical Technology Co.,Ltd
Address	102, 105, Zone 20, Huayin Industrial Port, No.618, Kexing Road (West), Wenjiang District, Chengdu 611137 Sichuan P.R.China
Phone No.	TEL: +86 18086852687
Fax No.	/
Name of contact person	Zhang Peiyong
Date Prepared	Nov.18th.2023

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86 755-86069197
Contact person	Liz Li
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Website	http://www.cefda.com

2. Device information

Trade name	Cold Compression Wrap Pro
Classification	II
Classification name	Massager, Powered Inflatable Tube
Product code	IRP; IME
Regulation No.	21 CFR 890.5650

3. Legally Marketed Predicate Device

Trade Name	Cryopush Cold Compression Device
Classification	II
510(k) Number	K222669
Product Code	IRP; IME

Manufacturer	Chengdu Cryo-Push Medical Technology Co., Ltd
Trade Name	Portable Therapeutix Squid Active Cold Compression device and Cold Pack for OTC Use
510(k) Number	K133483
Product Code	IRP, IME
Manufacturer	MEDIcept, Inc.

4. Device Description

Cold Compression Wrap Pro Device consists of a main unit and wraps which simulates kneading and stroking of tissue with the hands by use of inflatable pressure wraps. It is for temporary increase in circulation of the treated areas and temporary relief of minor muscle aches and pains. By inflating the air chambers and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient.

There are 4 different wraps for Shoulder, elbow/arm, low limbs (Calf and upper leg), ankle/foot. The wrap contains cold pack, and the cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

When the device is used for 30 minutes (Default time) at the operating temperature (5℃~ 40℃) specified in the user manual, the temperature of the cold pack is (-18℃ ~-4℃) (±2℃).

5. Intended use

The Cold Compression Wrap Pro is indicated for the temporary relief of minor muscle aches and pains.

The device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneading and stroking of tissues using an inflatable wrap.

The cold wrap is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

6. Substantial Equivalence Comparison

Item	Subject device	Predicate device K222669	Predicate device K133483	Comments
Device name	Cold Compression Wrap Pro	Cryopush Cold Compression Device	Portable Therapeutix Squid Active Cold Compression device and Cold Pack for OTC Use	/
model	A02-C-006	A02-P-001	not publicly available	/
Regulation number	21 CFR 890.5650, 21 CFR 890.5700	21 CFR 890.5650, 21 CFR 890.5700	21 CFR 890.5650, 21 CFR 890.5700	Identical
Classification	II	II	II	Identical
Product Code	IRP, IME	IRP, IME	IRP, IME	Identical
Intended use	The Cold Compression Wrap Pro is indicated for the temporary relief of minor muscle aches and pains. The device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneading and stroking of tissues using an inflatable wrap. The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.	The Cryopush Cold Compression Device is indicated for the temporary relief of minor muscle aches and pains. The device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneading and stroking of tissues using by an inflatable wrap. The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.	The Squid Active Cold Compression device and Cold Pack for OTC use is indicated for the temporary relief of minor muscle aches and pains. The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment. The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.	Identical

Item	Subject device	Predicate device K222669	Predicate device K133483	Comments
Treatment area/ Structure of Sleeves	Shoulder, elbow/arm, low limbs (Calf and upper leg), ankle/foot	Low limbs (Calf and upper leg)	Leg, foot, arm, shoulders, lower back, hands	Note
OTC or Rx	OTC	OTC	OTC	Identical
Environment of Use	Clinics, hospital, athlete training environments	Clinics, hospital, athlete training, and home environments	not publicly available	Note
Power source	100-240V~50/60Hz	100-240V~50/60Hz	120V 60 Hz, consumption 26W; AC adapter: 120V 60 Hz, consumption 36W Lithium battery	Identical to K222669
Principle of operation/ Mechanical characteristics	Intermittent compression 5 intensity settings 1-20 mmHg 2-40 mmHg 3-60 mmHg 4-80 mmHg 5-100 mmHg	Intermittent compression 5 intensity settings 1-20 mmHg 2-40 mmHg 3-60 mmHg 4-80 mmHg 5-100 mmHg	Intermittent compression 4 intensity settings 1-30 mmHg 2-50 mmHg 3-70 mmHg 4-85 mmHg	Identical to K222669 & Note
Working Time	10min, 20 min, 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min, 100 min, 110 min, 120 min, default as 30min	10min, 20 min, 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min, 100 min, 110 min, 120 min, default as 30min	15min	Identical to K222669
Pressure range	0-100mmHg	0-100mmHg	0-85mmHg	Identical to K222669
Pressure levels	20mmHg,40 mmHg,60 mmHg,80 mmHg,100 mmHg.	20mmHg,40 mmHg,60 mmHg,80 mmHg,100 mmHg.	30mmHg,40 mmHg,70 mmHg,85 mmHg	Identical to K222669
Pressure error range	±15mmHg	±15mmHg	not publicly available	Identical to K222669
Keep time	5s	10s	not publicly available	Substantial Equivalence
Deflation time	6S	20s	not publicly available	

Item	Subject device	Predicate device K222669	Predicate device K133483	Comments
Noise level	≤ 55dB	≤ 55dB	not publicly available	Identical
Wrap Material	Nylon with a PVC laminate	Nylon with a PVC laminate	Nylon with TPU backing wrap-yes	Identical to K222669
Patient contact	Non-conductive attachments	Non-conductive attachments	not publicly available	Identical to K222669
Single Wrap weight	low limbs (Calf and upper leg):480g; Ankle/foot: 338g; Shoulder: 388g; elbow/arm: 308g;	480g	not publicly available	Substantial Equivalence
Wrap Size	low limbs (Calf and upper leg): 330*610mm; Ankle/foot: 830*420mm; Shoulder: 1080*430mm; elbow/arm: 620*440mm;	330*610mm	not publicly available	
Cold pack weight	low limbs (Calf and upper leg):1030g; Ankle/foot: 1282g; Shoulder: 932g; elbow/arm: 632g;	1030g (±10%)	not publicly available	
Cold pack Size	low limbs (Calf and upper leg):570*300mm; Ankle/foot: 595*260mm; Shoulder: 520*360mm; elbow/arm: 440*370mm;	300*570mm	not publicly available	
Cold pack Operating temperature	-18℃~ -4℃ (±2℃)	-18℃~ -4℃ (±2℃)	not publicly available	Identical to K222669
Operating environment	Temperature: 5℃～ 40℃ (41℉～ 104℉) Relative humidity:	Temperature: 5℃～ 40℃(41℉～ 104℉) Relative humidity:	not publicly available	Identical to K222669

Item	Subject device	Predicate device K222669	Predicate device K133483	Comments
	10% ～ 90% Atmospheric pressure: 700~1060hpa	10% ～ 90% Atmospheric pressure: 700~1060hpa		
Transportation & Storage environment	Temperature: -25℃~55℃ (-13℉～131℉) Relative humidity: 10% ～ 90% Atmospheric pressure: 700~1060hpa	Temperature: -25℃~55℃（-13℉～131℉） Relative humidity: 10% ～ 90% Atmospheric pressure: 700~1060hpa	not publicly available	Identical to K222669

The subject device, Cold Compression Wrap Pro, is substantially equivalent to the predicate device **K222669** and **K133483**. This conclusion is based upon comparison on intended use, principle of operation and technological characteristics, etc.

7. Summary of Non-clinical Performance Testing

The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility

- IEC 60601-1:2005, AMDI:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

2) Software validation

The subject device contains an embedded software system. Software verification and validation testing were conducted as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", and the software for this device was considered as a "moderate" level of concern.

3) Performance

There are no FDA recognized consensus standards for this device. We tested the following items according to our internal standards,

- Product Appearance and Size
- Wrap Performance
- Function Test

4) Biocompatibility test

The subject device and the predicated device use the same patient contact material, and has the same nature of body contact and contact duration. Therefore, no biocompatibility test was conducted.

8. Clinical testing

N/A

9. Conclusions

The subject device, Cold Compression Wrap Pro, is substantially equivalent to the predicate device **K222669** and **K133483**. This conclusion is based upon comparison on intended use, principle of operation and technological characteristics, etc.