December 5, 2022

Chengdu Cryo-Push Medical Technology Co., Ltd
℅ Liz Li
Counselor
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1713A, 17th Floor, Block A, Zhonhhuan Times Square
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Shenzhen, Guangdong 518000
China

Re: K222669
Trade/Device Name: Cryopush Cold Compression Device
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IME
Dated: September 6, 2022
Received: September 6, 2022

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 (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,

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

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)*
K222669

Device Name
Cryopush Cold Compression Device

Indications for Use *(Describe)*

A02-P-001:

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.

A02-P-002:

The Cryopush A02-P-002 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.

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.

510(k) Summary

1. Contact Details

1.1 Applicant information

Applicant 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
Contact person	Zhang Peiyong
Date Prepared	Aug.10.2022

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
Contact person's e-mail	liz@cefda.com; grace@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Cryopush Cold Compression Device
Classification	II
Classification name	Massager, Powered Inflatable Tube
Product code	IRP IME
Regulation No.	21 CFR 890.5650 21 CFR 890.5700

3. Legally Marketed Predicate Device

Trade Name	Air Compression Therapy Device
510(k) Number	K193354
Product Code	IRP
Manufacturer	Shenzhen Dongjilian Electronics Co., Ltd

4. Device Description

Cryopush Cold Compression 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. The device includes two models A02- P-001 and A02- P-002. The A02- P-001 has one chamber, and A02- P-002 has 2 chambers. The A02- P-001 contains cold pack, and the cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.
When the A02- P-001 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

A02-P-001:
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.

A02-P-002:
The Cryopush A02-P-002 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.

6. Substantial Equivalence Comparison

Item	Proposed Device: (K222669)		Predicate Device: (K193354)	Comments
Regulation number	890.5650		890.5650	Same
Classification	II		II	Same
Model	A02-P-001	A02-P-002	S9019	Same
Product Code	IRP, IME		IRP	Substantial Equivalence
Intended use/Indications for use	The Cryopush Cold Compression Device is indicated for the temporary relief of minor muscle aches and pains. The device is	The Cryopush A02-P-002 is indicated for the temporary relief of minor muscle aches and pains. The device is	The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in	

Item	Proposed Device: (K222669)		Predicate Device: (K193354)	Comments
	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.	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.	people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.	
Treatment area/Structure of Sleeves	Low limbs (Calf and upper leg)		Low limbs (Foot, calf and upper leg)	Similar
OTC or Rx	OTC		OTC	Same
Environment of Use	Clinics, hospital, athlete training, and home environments		Clinics, hospital, athlete training, and home environments	Same
Power source	100-240V~50/60Hz		100~240V 50/60Hz	Same
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, default as 30min	20 minutes	Substantial Equivalence
Pressure range	0-100mmHg	0～215 mmHg	0~240 mmHg	Substantial Equivalence
Pressure levels	20mmHg,40 mmHg,60 mmHg,80 mmHg,100 mmHg.	100mmHg,160 mmHg, 215mmHg;	150mmHg; 185mmHg; 215mmHg	
Pressure error range	±15mmHg	±20mmHg	±25mmHg	
Keep time	10s		1-5s	Substantial Equivalence
Deflation time	20s		1-5s	
Working process	The pressure of the chamber gradually rises to the pre-determined air pressure level, then decompresses and the air pressure	Starting with the lower chamber and progressing up the upper chamber, each section compresses and the pressure gradually rise to the pre-determined air	**Mode 1:**Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the	Similar

Item	Proposed Device: (K222669)		Predicate Device: (K193354)	Comments
	drops. The cycle begins again.	pressure level, then decompresses and the air pressure drops. Once the upper chamber decompresses, the cycle begins again.	air pressure drops. Once the thigh section decompresses, the cycle begins again. **Mode 2:**Starting with the foot chamber and progressing up the thigh, each section compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All three sections then decompress simultaneously and the air pressure drops, then cycle begins again. **Mode 3:**include two stages, stage1: it works according to the method of mode 1, after the stage 1 is completed, it goes to stage 2(working according to the method of mode 2) without interruption time until finish the stage 2, then enter next cycle without interruption. Mode1⇄Mode2 The pressure sequence of mode 3 combines mode 1 and mode 2	
Noise level	≤ 55dB		≤ 65dB	Similar
Wrap Material	Nylon with a PVC laminate		Nylon with a Polyurethane laminate	Different
Patient contact	Non-conductive attachments		Non-conductive attachments	Same
Appearance				Different
Single Wrap weight	480g	210g	4.6 pounds (2023g)	
Wrap Size	330x610mm	615×255mm	73*26cm	

Item	Proposed Device: (K222669)		Predicate Device: (K193354)	Comments
Cold pack weight	1030g (±10%)	NA	NA	Different
Cold pack Size	300 x 570mm			
Operating environment	Temperature: 5℃～ 40℃ (41℉～ 104℉) Relative humidity: 10% ～ 90% Atmospheric pressure: 700~1060hpa		Temperature: 5℃- 40℃, Humidity: 5%- 90% non-condensing	Similar
Transportation & Storage environment	Temperature: -25℃~55℃（-13℉～131℉） Relative humidity: 10% ～ 90% Atmospheric pressure: 700~1060hpa		Temperature: - 20℃ ~55℃; Humidity:5%-90% non-condensing Atmospheric Pressure:75kPa-106kPa	

The subject device sequentially inflates and deflation inflatable chambers to simulate kneading and stroking of tissues for the temporary relief of minor muscle aches and pains. Prolonged use will not cause circulation issues.

The cold pack of A02-P-001 provides cold therapy for body surfaces, which can make capillaries constrict, reduce local congestion, can make nerve endings less sensitive and reduce pain. Within 30 minutes of operation, the temperature of the cold pack will be from -18℃ to -4℃, which will not bring potential harm to the patient. Its code is IME and the submission type is 510(K) Exempt. So, the difference of cold pack would not raise adversely impact on safety and effectiveness.

Although the treatment time range of subject device is 0 to 120mins, which seems to be larger than the predicate devices, but the default value is 30min which is suitable for daily use. In the process of use, the user can start or stop at any time by the power button on the hand controller, so the difference of Treatment time would not raise adversely impact on safety and effectiveness.

The subject device, Cryopush Cold Compression Device, is substantially equivalent to the predicate device (K193354). This conclusion is based upon comparison on intended use, technological characteristics and performances. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.

7. Non-clinical 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 60601-1-11:2015 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

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 software document of the subject device was determined according to Guidance for Industry and FDA Staff- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005

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

8. Clinical testing

N/A

9. Other information (such as required by FDA guidance/Test)

N/A

10. Conclusions

The subject device is substantially equivalent to the legally marketed predicate device Air Compression Therapy Device (K193354).