April 2, 2026

Chengdu Cryo-push Medical Technology Co.,Ltd
% Aria Yao
Regulatory Affairs Specialist
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K253076
Trade/Device Name: Cryopush Cold Compression Device (A02-P-001)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Codes: IRP, IME
Dated: June 18, 2025
Received: September 23, 2025

Dear Aria Yao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.04.02
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for Tushar Bansal, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253076

Device Name
Cryopush Cold Compression Device (A02-P-001)

Indications for Use *(Describe)*
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.

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
K253076

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	Aria Yao
Contact person's e-mail	aria@cefda.com; james_tsai@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Cryopush Cold Compression Device (A02-P-001)
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	Air Compression Therapy Recovery System
510(k) Number	K222669
Product Code	IRP, IME
Manufacturer	Cryo-Push Medical Technology Co.,Ltd

4. Device Description

The Cryopush Cold Compression Device consists of a main unit and wraps. Main unit inflates the wrap to a specified pressure of 20 mmHg, 40 mmHg, 60 mmHg, 80 mmHg or 100 mmHg (set by the user), and once the pressure reached the targeted level, it will hold for 10 seconds before releasing, then decompresses and the air pressure drops. The cycle begins again. Default working time is 30 minutes. Built-in rechargeable lithium batteries allow the system to be completely portable for use anytime and anywhere. 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 a default time of 30 minutes at the operating temperature (5℃~ 40℃) specified in the user manual, the operating temperature of the cold pack is (-18℃~+2℃) (±2℃).

5. Intended use

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.

6. Substantial Equivalence Comparison

Item	Proposed Device:	Predicate Device (K222669)		Comments
Regulation number	890.5650	890.5650		Same
Classification	II	II		Same
Model	A02-P-001	A02-P-001	A02-P-002	Same
Product Code	IRP, IME	IRP, IME		
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 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 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 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.	Same
Treatment area/Structure of Sleeves	Leg (Ankle, Calf and upper leg), Hip, Arm (Hand/wrist, Shoulder, Elbow), Back (Neck, Back, Lower Back)	Low limbs (Calf and upper leg)		Note 1
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,	10min, 20 min, 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min, 100 min,	10min, 20 min, 30 min, 40 min, 50 min, 60 min, default as 30min	Same

Item	Proposed Device:	Predicate Device (K222669)		Comments
	default as 30min	110 min, 120 min, default as 30min		
Pressure range	0-100mmHg	0-100mmHg	0～215 mmHg	Same
Pressure levels	20mmHg,40 mmHg,60 mmHg,80 mmHg,100 mmHg.	20mmHg,40 mmHg,60 mmHg,80 mmHg,100 mmHg.	100mmHg,160 mmHg,215mmHg;	
Pressure error range	±15mmHg	±15mmHg	±20mmHg	
Keep time	10s	10s		Same
Deflation time	20s	20s		
Working process	The pressure of the chamber gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. The cycle begins again.	The pressure of the chamber gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. The cycle begins again.	Starting with the lower chamber and progressing up the upper chamber, each section compresses and the pressure gradually rise to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the upper chamber decompresses, the cycle begins again.	Same
Noise level	≤ 55dB	≤ 55dB		Same
Wrap Material	Nylon with a PVC laminate	Nylon with a PVC laminate		Same
Patient contact	Non-conductive attachments	Non-conductive attachments		Same
Appearance				Note 2
Wrap Size	A02-C-020: 330x610mm; A02-P-001-A1: 445x850mm; A02-P-001-B: 515x425mm; A02-P-001-B1: 970x570mm; A02-P-001-B2: 970x570mm; A02-P-001-E:	330x610mm	615×255mm	

Item	Proposed Device:	Predicate Device (K222669)		Comments
	1420x335mm; A02-P-001-E2(M): 1230x800mm; A02-P-001-E2(L): 870x1230mm; A02-P-001-E4: 1210x370mm; A02-P-001-F: 470x440mm; A02-P-001-G: 620x325mm; A02-P-001-J: 1085x480mm.			
Operating temperature of the cold wrap	(-18℃~+2℃) (±2℃)	(-18℃~-4℃) (±2℃)		Note 3
Operating environment	Temperature: 5℃～40℃(41℉～ 104℉) Relative humidity: 10% ～ 90% Atmospheric pressure: 700~1060hpa	Temperature: 5℃～ 40℃(41℉～ 104℉) Relative humidity: 10% ～ 90% Atmospheric pressure: 700~1060hpa		Same
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		

Note 1: The treatment areas of the lower limbs are covered by predicate device. The additional treatment areas of the hips, arms, and back do not raise different questions of safety and effectiveness, and lab bench testing demonstrates acceptable safety and performance. These additional treatment areas have also been included in other legally marketed tube massager devices.
Note 2: Although the subject device is different from predicate devices in the wrap size, the difference in design would not adversely impact safety and effectiveness.
Note 3: The operating temperature range of the cold wrap of the subject device is covered by that of the predicate device. The difference does not raise different questions of safety and effectiveness.

The subject device, Cryopush Cold Compression Device, is substantially equivalent to the predicate device. This conclusion is based upon comparison on intended use, technological characteristics and applicable performance standards. 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
IEC 62133-2:2017, IEC 62133-2:2017/AMD: 2021: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
AIM 7351731 Rev. 3.00: Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
IEEE ANSI C63.18-2014: American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters

2) Software validation
The software document of the subject device was determined according to Guidance for Industry and FDA Staff- Content of Premarket Submissions for Device Software Functions, issued on June 14, 2023

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 and Function Test
    - Service life verification
    - Atmospheric condition testing
    - Stacking test
    - Vibration test
    - Drop test
    - Unpacking and inspection
    - Stress resistance
    - Air pressure release accuracy, rupture and deformities testing

8. Clinical testing

N/A

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

N/A

10. Conclusions

Non-clinical testing and technological comparison show that the subject device is substantially equivalent to the legally marketed predicate device.