December 8, 2022

Huizhou XINYI Technology Co., LTD.
Jason Ye
Manager Regulatory Affairs, Technical Regulation Department
Area (Building 3), Changbu Village
Xinwei, Huiyang District
Huizhou, Guangzhou 516200
China

Re: K221862
Trade/Device Name: YY-A02-B Overlapped Compression Therapy
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: December 5, 2022
Received: December 5, 2022

Dear Jason Ye:

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,

Heather L. Dean -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221862

Device Name
YY-A02-B Overlapped Compression Therapy

Indications for Use *(Describe)*
The Overlapped Compression Therapy is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Overlapped Compression Therapy simulates kneading and stroking of tissues by using an inflatable garment.

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.

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510(k) Summary

K221862

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Overlapped Compression Therapy is provided below.

1. SUBMITTER

Applicant:	Huizhou XINYI Technology Co., LTD Area (Building 3), Changbu Village, Xinwei, Huiyang District, Huizhou city, Guangdong Province, P.R.China Tel: +86 752 3533308 / +8618320209888 Fax: +86 752 3522225
Contact:	Jason Ye Title: Quality Manager Phone: +86 18129657928 Fax: +86 752 3522225 E-mail: 13728650049@163.com
Date Prepared:	October 10, 2022

2. DEVICE

Device Common Name:	Overlapped Compression Therapy
Device Trade Name:	YY-A02-B Overlapped Compression Therapy
Classification Name:	Massager, Powered Inflatable Tube
Regulation:	21 CFR 890.5650
Primary Product Code:	IRP
Regulatory Class:	Class 2
Panel:	Physical Medicine

3. PREDICATE DEVICE

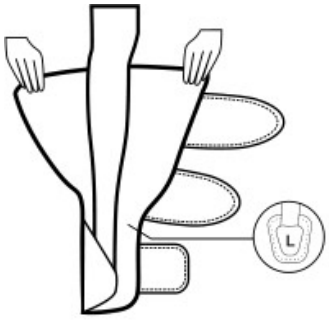
Predicate Device: K193354 - Air Compression Therapy Device (Shenzhen Dongjilian Electronics Co., Ltd.)

4. DEVICE DESCRIPTION

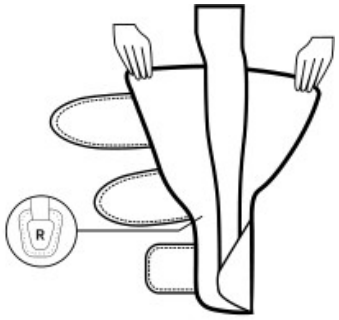
The Overlapped Compression Therapy consists of leg sleeve and control device working together as one unit. The Overlapped Compression Therapy mainly forms the circulating pressure on the limbs and tissues by repeatedly inflating and deflating the multi cavity chambers in sequence, and evenly, orderly and properly extrudes the distal end of the limbs to the proximal end of the limbs.

The donning instructions are shown below:

1) The tracheal interface is marked ‘L’ and ‘R’, please wear correctly.



Left Leg Sleeve



Right Leg Sleeve

2) Wear the warps on your legs correctly.

3) Fix all the velcros according to your size, don't wrap too tight.

5. INTENDED USE/INDICATIONS FOR USE

The YY-A02-B Overlapped Compression Therapy is intended to be used in a home and/or clinical setting for:

The Overlapped Compression Therapy is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Overlapped Compression Therapy simulates kneading and stroking of tissues by using an inflatable garment.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

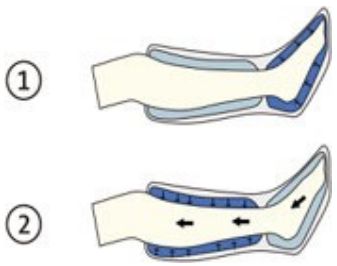
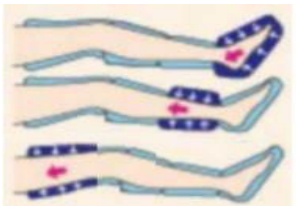
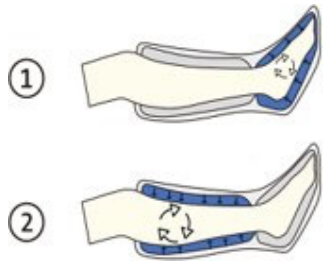
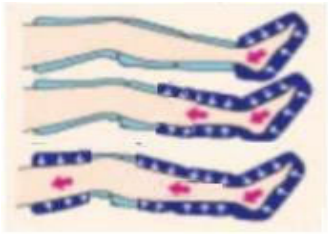
Both the predicate device and subject device are indicated for the temporary relief of minor muscle

aches and pains and for temporary increase in circulation to the treated areas.
In conclusion, the minor differences of the indications for use do not change the fundamental intended use of the YY-A02-B Overlapped Compression Therapy

Technological Comparisons

Table below compares the key technological features of the subject device to the predicate device. The features in gray are features which are different between the predicate device and the subject device.

Comparison	Subject device (K221862)	Primary Predicate device (K193354)	Comparison
Manufacturer	Huizhou XINYI Technology Co., LTD	Shenzhen Dongjilian Electronics Co.,Ltd.	N/A
510(K) number	K221862	K193354	N/A
Model name	YY-A02-B	S9019	N/A
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Same
Type of compression	Air pressure massage	Air pressure massage	Same
Indications for Use (IFU)	The Overlapped Compression Therapy is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Overlapped Compression Therapy simulates kneading and stroking of tissues by using an inflatable garment.	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 people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.	Same
Mode of compression	Mode 1 Sequence: Starting with the foot chamber as progressing up the chamber for gradually rises to the predetermined air pressure level, then decompresses the air pressure drops, then the calf chamber function working. Once the calf section decompresses, the cycle begins again.	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 air pressure drops. Once the thigh section decompresses, the cycle begins again.	Same

		Mode 1 follows this pressure sequence: 	
	Mode 2 Circulation: Select only one part to massage where the user's needs, which can be used to massage the foot or the calves separately. After selecting the massage pressure (50 mm-Hg/ 90 mm-Hg/130 mm - Hg/170 mm-Hg/210 mm-Hg) according to the user needs, relieve muscle fatigue and soreness through a cyclic massage of progress-up/ decompresses. 	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 2 follows this pressure sequence: 	Same

	Mode 3 Whole: Which is that the foot and calf are massaged at the same time after selecting the massage pressure(50 mm-Hg/ 90 mm-Hg /130 mm-Hg/170 mm-Hg/210 mm-Hg). The foot and calf muscle were massaged through progress-up/decompresses action, which can relax or reduce the fatigue and soreness of calf and foot muscles 	Mode 3: include two stage, stage 1: it work according to the method of mode 1, after the stage 1 is completed, it go 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	Same
Level of air pressure and pressure range	Level 1: 50mmHg Level 2: 90mmHg Level 3: 130mmHg Level 4: 170mmHg Level 5: 210mmHg	3 levels settings: low level:150mmHg Mid level:185mmHg High Level: 215mm	Similar ***Note 1***
Pressure error range	±10mmHg	±25mmHg	Different ***Note 2***
Compression cycle time	8s-1 min 45s	Range of 25 sec to 3 min 40 sec	Similar ***Note 3***
Anatomical locations of applications	Foot Calf	Low limbs (Foot, calf and upper leg)	Similar ***Note 4***
Sleeve materials	Polyester	Nylon with a Polyurethane laminate	Different ***Note 5***
Number of air chambers	2 Chambers	3 Chambers	Different ***Note 6***

Inflation & deflation time	Inflation time:≤20s Deflation time:7s	Inflation time:3-30s Deflation time:1-5s	Similar ***Note 7***
Power consumption	8W	12W	Different ***Note 8***
Transportation environment	Temperature:-20℃ to 70℃（-4°F to 158°F ） Humidity:0% to 90% RH Atmospheric Pressure:50kPa to 106kPa	Temperature: -20℃~55℃ Humidity:5%-90% non-condensing Atmospheric Pressure:75kPa-106kPa	Different ***Note 9***
Standards complied with	ES60601-1 IEC60601-1-2 ISO 10993-5 ISO 10993-10 IEC60606-1-11	ES 60601-1 IEC60601-1-2 ISO 10993-5 ISO 10993-10 IEC 60601-1-11	Same
Weight	2.3 pounds	4.6 pounds	Different ***Note 10***
Recommended treatment time	20 minutes	20 minutes	Same

Similarity and Difference

The YY-A02-B Overlapped Compression Therapy has been compared with the Air Compression Therapy Device. The subject device has same intended use and principle of operation, similar technological characteristics as that of predicate device. Although there are several specifications that are different between the subject device and predicate device, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate devices do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in safety and performance claims.

Note 1: The level of air pressure and pressure range is different. the level of air pressure of the subject is 5 level and the predicate device is 3 level. The minimum air pressure (0 mmHg) of subject device is the same as the predicate device. the air pressure of subject device (210 mmHg) is within the range of the predicate device. Additionally, the subject device conforms to ANSI/AAMI ES60601-1 and ISO 14971, so the small differences do not affect the safety and effectiveness. Although the "air pressure level /compression levels" of subject device is different to the predicate devices, but they output air pressure range are similar, so the pressure level different do not affect the safety and effectiveness

Note 2: The subject device has a smaller pressure error range than the predicate device. So the small difference do not affect the safety and effectiveness.

Note 3: Although the "Cycle time" of subject device is different the predicate devices, but the range of cycle time is less than predicate device. So the small difference do not affect the safety and effectiveness

Note 4: The "anatomical locations of applications" of the subject device is different. It not contains the upper leg. The small difference do not affect the safety and effectiveness.

Note 5: Although the "sleeve materials" of the subject device is different from the predicate device, but the subject device complies with the requirements of the biocompatibility standards. So the difference do not affect the safety and effectiveness.

Note 6: Although the "Number of chambers" of subject device is different to the predicated device, but due to the chamber number only determines the applicable treatment site, while the "applicable treatment site" and "Indications for Use" of subject device is within the range of predicated device. So the differences do not affect the safety and effectiveness.

Note 7: Although the "Inflation & deflation time" of subject device if different to the predicated device. For the safety: the subject device has compliance with IEC 60601-1 and ISO 14971 standards. And the subject device has designed the pressure sensor to protection the over-pressure, so the subject device was safety. For the effectiveness: since the treatment mode, treatment pressure and cycle time of the subject device is similar to the predicate devices, so we can be considered that

the subject device and predicate device had similar effectiveness. Based on the above analysis, can be considered the small difference will not affect the safety or effectiveness issue

Note 8: Although the "power consumption" of the subject device is different than the predicate devices, they both comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness.

Note 9: Although the "Transportation environment" of the subject device is different than the predicate devices, they comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness.

Note 10: Although the "Weight" between the predicate devices and subject device is different, they are both complied with ANSI/AAMI ES60601-1 and IEC 60601-1-2, so the differences do not affect the safety and effectiveness

Substantial Equivalence Conclusion

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

To establish the substantial equivalence of the Overlapped Compression Therapy, XINYI conducted functional and system level testing to validate the performance of the device. The results of the bench testing show that the subject device meets its specifications and is substantially equivalent to the predicate device.

In addition, XINYI has conducted testing to ensure the subject device meet relevant consensus standards.

7. PERFORMANCE DATA

Biocompatibility Testing

The Overlapped Compression Therapy is patient contacting, therefore biocompatibility data is required.

In accordance with ISO 10993, it is surface devices that contact intact skin for a prolonged duration and the appropriate testing is Cytotoxicity, Skin Irritation and Sensitization. The subject device conducted and passed all biocompatibility testing.

Software Verification and Validation Testing

Per FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff", software verification and validation testing was conducted, and documentation was provided. Verification of the Overlapped Compression Therapy was conducted to ensure that the product works as designed. Validations was conducted to check the design and performance of the product.

Electrical safety and electromagnetic compatibility (EMC)

The Overlapped Compression Therapy has been tested for conformance with the following electromagnetic compatibility and electrical safety standards.

- ANSI / AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential

performance

- IEC60601-1-2:2014 (Fourth Edition) Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

Bench Testing

To establish the substantial equivalence of the Overlapped Compression Therapy, XINYI conducted functional and system level testing to validate the performance of the device. The results of the bench testing show that the subject device meets its specifications and is substantially equivalent to the predicate device.

In addition, XINYI has conducted testing to ensure the subject device meet relevant consensus standards.

- IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-2: 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.
- IEC60601-1-6: 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Accuracy testing for pressure and time to ensure that the device can achieve the intended maximum pressure and maintain it for the intended treatment time.

Seam strength testing to ensure that the seams of the device do not burst if maximum pressure is exceeded in the device.

Failure mode testing to indicate how the device mitigates the risk of over-pressurization if there is a software failure and the device starts to exceed maximum intended pressure.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

Based on the detailed comparison between the predicate device and the subject device, the performance testing and conformance with applicable standards, the Overlapped Compression Therapy can be found substantially equivalent to the predicate device.