December 21, 2023

Medella Health Limited
℅ Samantha Nava
Managing Director
Tilia Bridge
1506 Summer City Dr
Houston, Texas 77047

Re: K223729
Trade/Device Name: FLOWpresso
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IRT
Dated: December 7, 2023
Received: December 12, 2023

Dear Samantha Nava:

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,

Heather L. Dean -S

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)*
K223729

Device Name
FLOWpresso

Indications for Use *(Describe)*
The Flowpresso Device combines heat and compression therapy. Flowpresso is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy are indicated.

Flowpresso is intended to be used by, or on the order of, licensed health care professionals based in rehabilitation facilities, outpatient clinics and athletic training 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.

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510(k) SUMMARY

Medella Health Ltd K223729

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

Date: 7th December 2023

Submitter: Medella Health Ltd
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Device Name and Classification:

Trade Name:	Flowpresso
Common Names:	Heat and Compression Therapy
Classification:	Class II
Regulation Number:	21CFR 890.5650, Powered Inflatable Tube Massager
Classification Panel:	Physical Medicine
Product Code:	IRP, IRT

Predicate Device:

	Subject	**Predicate**
Trade Name:	Flowpresso	Therm-X
Common Name:	Heat and Compression Therapy	Heat and/or Cold Compression Therapy
510(k) Submitter/Holder:	Medella Health Ltd	Zenith Technical Innovations, LLC. (Zenith)
510(k) Number:	K223729	K193550
Classification:	Class II	Class II
Regulation Number:	890.5650 Powered Inflatable Tube Massager	890.5650 Powered Inflatable Tube Massager
Classification Panel:	Physical Medicine	Physical Medicine
Product Code:	IRP, IRT	IRP, ILO, JOW

1 Device Description

The Flowpresso Compression Device is an AC powered, software-controlled multimodality device, designed to be used in a clinical setting, and under the direction, prescription, or

supervision of a licensed healthcare professional.

Flowpresso is a non-invasive physical suit that delivers compression, and heat therapy. The suit has air pressure and heat cables that are connected to a computerized power unit that controls ranges and duration of treatment.

The Flowpresso consists of various inflatable wraps that cover the back/hip and extremities of a fully clothed patient with Velcro fasteners. These multi patient use garments are designed to accommodate different anatomical shapes and sizes of patients that can be cleaned and disinfected in between uses to be reused for different patients. The suit has 22 individual internal chambers that inflate sequentially before its predecessor completely deflates, to provide a progressive pressure without any flow back.

Flowpresso is controlled by an intuitive touch screen computer interface, allowing the user to manage the therapy modalities as well as easily adjust the monitor treatment times, temperature, and compression settings. Flowpresso has two separate modes: sports or relaxation, with different cycles to deliver a specific and individual experience that is supervised by a health care provider. The therapy lasts forty (40) minutes where the health provider will be available to make any adjustments throughout the duration of therapy.

The session begins with air pressure to give the patient a comfortable increased pressure, followed by heat. The health care provider is responsible for adjusting settings of pressure/heat to ensure the patient is comfortable for the entirety of the forty (40) minute session.

2 Indications for Use

The Flowpresso Device combines heat and compression therapy. Flowpresso is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy are indicated.

Flowpresso is intended to be used by, or on the order of, licensed health care professionals based in rehabilitation facilities, outpatient clinics and athletic training settings.

3 Risk Analysis Method

Flowpresso was assessed to determine the risks to health, associated with the device and evaluate risks related to safety, effectiveness, and usability. A risk analysis was conducted in according with ISO 14971:2007 and ISO14971:2012, Medical devices – Application of risk management to medical devices. All risks have been found acceptable.

4 Substantial Equivalence Information

Flowpresso is equivalent to Therm-X (K193550) by Zenith Technical Innovations, LLC. (Zenith), currently on the market. Flowpresso has the same intended use and indications for use, as the predicate device and uses equivalent overall design and operating principals as the predicate device.

The table below provides a detailed comparison of Flowpresso to the predicate device.

Detailed Comparison of the Subject and Predicate Device

Characteristic	Predicate Device Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Indications for Use	Therm-X (Therm-X Home and Therm-X AT) combines cold, heat, contrast, and compression therapy. Therm-X is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to treat post traumatic and postsurgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) indicated. Therm-X (Therm-X Home and Therm-X AT) is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	The Flowpresso Device combines heat and compression therapy. Flowpresso is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy are indicated. Flowpresso is intended to be used by, or on the order of, licensed health care professionals based in rehabilitation facilities, outpatient clinics and athletic training settings.		X	The major difference between the subject and predicate device is Therm-X also combines cold and contrast.

Characteristic	Predicate Devices Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Intended Users	Health Care Professionals and lay users (under prescription)	Health Care Professionals		X	Flowpresso is not intended for home use.
Number of patients that can be treated at one time	One	One	X		
Two programmable Cycles	Configuration of two programmable cycles	Configuration of two programmable cycles	X		

Functions

Treatment Time	Custom: 3-40 minutes	01-40 minutes	X		
Heat Therapy	Default: 105°F, 107°F, 110°F Custom: 105°F – 110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F – 107°F	Default: 86°F – 104°F		X	Flowpresso operates at a lower temperature

Characteristic	Predicate Devices Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Compression Pressure Levels	Available in following levels: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg) Calf: 50 – 70 mmHg Foot: 90 – 130mmHg	5-130mm/Hg		X	Flowpresso delivers up to 130mm/Hg. Pressure range is dependent on patient comfort levels and are adjusted in real-time.
Static or Intermittent Pressure	Both	Both	X		
Power Down	Available	Available	X		
Password Protection	Available	Not Available		X	
Storage Cycle Usage Data	Available	Not Available		X	

Physical Unit

Characteristic	Predicate Device Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Dimensions (W x H x D)	10.5” x 9” x 15”	12” x 6” x 15.5”	X		
Weight	15 pounds when full of coolant	18 pounds	X		
Heating Mechanism	Thermoelectric	Thermotherapy		X	Thermotherapy consists of application of heat or for the purpose of changing the cutaneous, intra-articular and core temperature of soft tissue with the intention of improving the symptoms of certain conditions.
User Interface	Touch Screen	Touch Screen	X		

Electrical

Line voltage	100-240V	110-220V	X		
Line Frequency	50/60 Hz	50/60 Hz	X		
Electrical Safety Standards	ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA C22.2 No. 60601-1:2014 Type B IEC 60601-1-2	ANSI/AAMI ES60601-1:2005 + A1:2012 IEC 60601-1:2005 + A1:2012 EN60601-1:2006 +A1:2013	X		

Environment

Characteristic	Predicate Device Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Operating Temperature	60°F – 80°F (16°C – 27°C)	60°F – 80°F (16°C – 27°C)	X		
Storage Temperature	33°F – 122°F (1°C - 50°C)	33°F – 122°F (1°C - 50°C)	X		
Operating Humidity	Below 60% Noncondensing	Below 60% Noncondensing	X		
Storage Humidity	Below 60% Noncondensing	Below 60% Noncondensing	X		
Operating Atmospheric Pressure and Altitude	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000 m))	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000m))	X		

Accessories/Garments

Characteristic	Predicate Device Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Various anatomical thermal/compression garments for: Back/Hip, arm, leg, feet	X		Both devices are intended to be an upper body, lower body, or full body experience, which is based on the patients' individual needs.
Patient Contacting Material	Thermal garment reusable (multi-patient) - 30 denier nylon coated in urethane. DVT – 200 denier nylon coated in urethane.	Needle cotton, non-conductive and non-woven lining. All encompassed with a PVC material.	X		Flowpresso device is PVC material that internally holds needle cotton, non-conductive heat, and non-woven lining.
Multi-Patient Use and Single-Patient Use Wraps	Multi-Patient Use and Single-Patient Use Available	Multi-Patient Use		X	Flowpresso wraps are not available for single use
Biocompatibility	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	X		
Garment Flammability Testing	-	16 CFR 1610 Standard for the Flammability of Clothing Textiles		X	Flowpresso material was tested to meet safety standards.
Sterile/Non-Sterile	Non-sterile only	Non-sterile only	X		

Characteristic	Predicate Device Therm-X	Subject device Flowpresso	Similar	Different	Comparison
Cleaning Disinfection Validation of Labeling	Yes- for Multi-Patient use reusable wraps	Yes- for Multi-Patient use reusable wraps	X		
Human Factors testing to confirm intended users have found instructions for cleaning and disinfection easy to use	Yes- for Multi-Patient use reusable wraps	Yes- for Multi-Patient use reusable wraps	X		
Expected Life of Garments	Based on frequency of use and continued functional performance	Based on frequency of use and continued functional performance	X		
Validation of repeated cleaning and disinfection for reusable garments	Yes- for Multi-Patient use reusable wraps	Yes- for Multi-Patient use reusable wraps	X		

5 Testing:

Flowpresso was verified and validated in accordance with documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the type of tests performed.

Electromagnetic Compatibility / Electrical Safety:
Electromagnetic Compatibility/Electrical Safety testing was performed in accordance with the following standards:

- ANSI/AAMI ES60601-1:2005 + A1:2012. Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1:2005 + A1:2012. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- EN60601-1:2006 +A1:2013. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Verification results indicated that the device is safe.

Biocompatibility:
The Flowpresso patient contact materials were verified in accordance with the following standards:

- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Material Heat Testing:
The Flowpresso garment material testing was conducted in accordance with 16 CFR 1610 Standard for the Flammability of Clothing Textiles and the Test Procedure as per 16 CFR 1610.6. According to the test result, the submitted sample met the class 1 - normal flammability requirements defined in 16.CFR 1610. Further testing was conducted in accordance with IEC 60601-2-35:2021 Medical Electrical equipment Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use showing that all pieces remain well within tolerance of 40°C.

6 Cleaning, Disinfection and Shelf-Life Testing:
Flowpresso garments are intended for use over clothed skin only. They are provided non-sterile and not intended to be user sterilized. Cleaning instructions are provided for multi-patient use garments.

The Flowpresso components and garments do not have a definitive shelf live based on

packaging or time. Expected life is based on frequency of use and continued functional performance. Durability test has been performed and has confirmed the safe use and disinfection of a Flowpresso garment for the duration of the garment's life without evidence of deterioration of the garment due to cleaning.

7 Software Validation:

Medella Health has conducted software validation testing on the Flowpresso software and confirmed that Flowpresso software meets its performance requirements and specifications. Software Validation has been completed according to an established Validation procedure and FDA Guidance Documents and Industry Standards:

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

The Software is a Moderate Level of Concern as per FDA guidance. All required items related to software as required by FDA guidance have been included in this submission.

8 Performance – Bench:

Flowpresso has been tested for performance to verify the proper operation of the system. Test and verification results indicate that Flowpresso conforms to its predetermined specifications and operates within safety limits.

The following Tests have been performed:

- Pressure Accuracy Test
- Seam Strength Test
- Hose Integrity Test
- Failure Mode Test
- Garment V&V Testing Report

9 Substantial Equivalence Conclusions

In conclusion, the intended use for Flowpresso is substantially equivalent to that of the predicate device. The technological characteristics comparison demonstrates that Flowpresso is equivalent to the predicate device, and the testing shows that Flowpresso is substantially equivalent to the predicate device and assures that Flowpresso is as safe and effective as the predicate devices.