June 17, 2022

CERAGEM Co, Ltd.
% Joyce Kwon
CEO
Provision Consulting Group, Inc.
100 Barranca St. Suite 700
West Covina, California 91791

Re: K220572
Trade/Device Name: Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-Function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB, IRP
Dated: May 16, 2022
Received: May 19, 2022

Dear Joyce Kwon:

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,

Amber Ballard, PhD
Assistant Director
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)*
K220572

Device Name
Ceragem Automatic Thermal Massager, Model CGM-MB-1701 & CGM-MB-1702

Indications for Use *(Describe)*
The intended use of the Ceragem Automatic Thermal Massager,
Model CGM MB-1701 & CGM MB-1702 is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for:
-Temporary relief of minor muscle and joint pain stiffness
-Temporary relief of minor joint pain associated with arthritis
-Temporary increase in local circulation where applied
- Relaxation of muscles

The Air Cell Massager (only CGM MB-1701) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The Air Cell Massager stimulates 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

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Date Prepared
June 17, 2022

Device Information
- Trade Name: Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702
- Common Name: Physical Therapy Table
- Classification Name: Multi-function physical therapy table
- Regulation Number: 21 CFR 890.5880
- Device Class: Class II
- Product Code: JFB, IRP
- 510(k) Identification Number: K220572

Primary Predicate Devices
- Ceragem Automatic Thermal Massager Model CGM-MB-1701 & CGM-MB-1702, K202937

The predicate has not been subject to a design-related recall.

Reference Device:
- Air Compression Therapy Device, K193354

Prior Submission Information
None

Indication for Use
The intended use of the Ceragem Automatic Thermal Massager,
Model CGM MB-1701 & CGM MB-1702 is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for:
- Temporary relief of minor muscle and joint pain stiffness
- Temporary relief of minor joint pain associated with arthritis
- Temporary increase in local circulation where applied

- Relaxation of muscles

The Air Cell Massager (only CGM MB-1701) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The Air Cell Massager stimulates kneading and stroking of tissues by using an inflatable garment.

Device Description

The Ceragem Automatic Thermal Massager with Air Cell Massager is an updated version of the predicate device with an addition of a leg massaging feature.
This feature utilizes an "air compression transfer," and its principle is as follows:
Air Cell Massager consists of an air pump, air pressure sensor, and sleeves working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses; each sleeve has 4 compression chambers. The compression massage direction is from foot to thigh. By inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The sleeve works under the action of sensor and microprocessor. Software controls the timing and pressure cognized to the sensor, cycling airflow into and out of sleeves to compress body.

Substantial Equivalent Comparison Chart with Primary Predicate Device

	Subject Device	Primary Predicate Device	Comparison
Device Name	Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702	Ceragem Automatic Thermal Massager, Model CGM MB-1701& CGM MB-1702	N/A
Manufacturer	Ceragem International, Inc.	Ceragem International, Inc.	
510(k) Number	K220572	K202937	
Regulation Number	21 CFR 890.5880, 21 CFR 890.5650	21 CFR 890.5880	
Product Code	JFB, IRP	JFB	
Indications for Use (IFU)	The intended use of the Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702 is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for: -Temporary relief of minor muscle and joint pain stiffness -Temporary relief of minor joint pain associated with arthritis -Temporary increase in local circulation where applied - Relaxation of muscles The Air Cell Massager (only CGM MB-1701) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The Air Cell Massager stimulates kneading and stroking of tissues by using an inflatable garment.	The intended use of the Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702 is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for: - Temporary relief of minor muscle and joint pain stiffness - Temporary relief of minor joint pain associated with arthritis - Temporary increase in local circulation where applied - Relaxation of muscles	Similar
Rated Voltage	100-127Vac 50/60Hz	100-127Vac 50/60Hz	Same

Home Use		Yes	Yes	Same
Style		Flood Model (Massage Bed)	Flood Model (Massage Bed)	
Components		Main Table	Main Table	
		Supporting Mat	Supporting Mat	
		Remote Control	Remote Control	
		3-Sphere projector	3-Sphere projector	
		Abdominal Vibration Projector	Abdominal Vibration Projector	
		Power cord	Power cord	
		Outer fabric	Outer fabric	
		Head cushion	Head cushion	
		Projector Cover	Projector Cover	
		Air Cell Massager	Calf Massager	Different (Note 1)
Remote Control		Yes	Yes	
Operation Method		Auto / Manual	Auto / Manual	
Infrared Emission Spectrum		Ceramic: 5~20 Epoxy Carbon Panel: 5~20	Ceramic: 5~20 Epoxy Carbon Panel: 5~20	
Heating Device	**Voltage**	24V	24V	
	Power	28.8W	28.8W	
Temperature Range		• Internal: 30°C - 65°C (86°F - 149°F) • External, Main, Auxiliary: 30°C - 60°C (86°F - 140°F)	• Internal: 30°C - 65°C (86°F - 149°F) • External, Main, Auxiliary: 30°C - 60°C (86°F - 140°F)	
Distance of the Internal Projector		710mm	710mm	
Intensity Level		1~9 (12.9~69.2mm)	1~9 (12.9~69.2mm)	
Extra Overheating Protection		Yes	Yes	

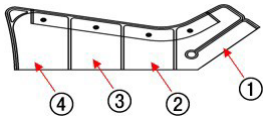
Moving Device		Geared DC Motor	Geared DC Motor	Same
Limit Detector		Limit Switch	Limit Switch	
Temperature Sensor		Thermistor	Thermistor	
Control Method		Microcontroller	Microcontroller	
Tugging Method		Wire-Chain	Wire-Chain	
Material	**Main/Supporting Frame**	Steel, ABS	Steel, ABS	
	Outer Fabric	Polyester, Cotton, Rayon, Polyurethane	Polyester, Cotton, Rayon, Polyurethane	
	Main Mat/Supporting Mat	Nylon Polyurethane	Nylon Polyurethane	
Projectors	**Internal Projector**	Ceramic Rollers	Ceramic Rollers	
	External Projector	Ceramic Heads Projector	Ceramic Heads Projector	
Mat Dimensions		• When spread out : 728.2mm x 2012.4mm x 431.5mm (±5mm) • When folded : 728.2mm x 2044mm x 431.5mm (±5mm)	• When spread out : 728.2mm x 2012.4mm x 431.5mm (±5mm) • When folded : 728.2mm x 2044mm x 431.5mm (±5mm)	
Weight		Weight: 62kg for CGM MB-1701, 57kg for CGM MB-1702	Weight: 62kg for CGM MB-1701, 57kg for CGM MB-1702	
Mode		Mode A	Mode A	
		Mode 1	Mode 1	
		Mode 2	Mode 2	
		Mode 3	Mode 3	
		Mode 4	Mode 4	
		Mode 5	Mode 5	

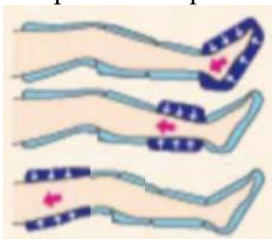
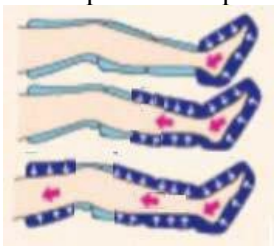
	Mode 6	Mode 6	
	Mode 7	Mode 7	
	Mode 8	Mode 8	
	Mode 9	Mode 9	
	Mode 10	Mode 10	
	Mode 11	Mode 11	
	Mode 12	Mode 12	
	Mode 13	Mode 13	
	Mode 14	Mode 14	
	Mode 15	Mode 15	
	Mode 16	N/A	
	Intensive Mode	Intensive Mode	
	Semi-Automatic Mode	Semi-Automatic Mode	
	Semi-Automatic Master Mode	Semi-Automatic Master Mode	
	Manual Mode	Manual Mode	
	Manual Master Mode	Manual Master Mode	
	Abdominal Vibration Projector Mode	Abdominal Vibration Projector Mode	
	Air Massage Mode	Calf Mode	Different (Note 1)

Substantial Equivalent Comparison Chart with Reference Device

	Subject Device	**Reference Device**	**Comparison**
Device Name	Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702	Air Compression Therapy Device	N/A
Manufacturer	Ceragem International, Inc.	Shenzhen Dongjiilian Electronics Co., Ltd.	

510(k) Number	K220572	K193354	N/A
Regulation Number	21 CFR 890.5880, 21 CFR 890.5650	21 CFR 890.5650	
Product Code	JFB, IRP	IRP	
Indications for Use (IFU)	The intended use of the Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702 is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for: -Temporary relief of minor muscle and joint pain stiffness -Temporary relief of minor joint pain associated with arthritis -Temporary increase in local circulation where applied - Relaxation of muscles The Air Cell Massager (only CGM MB-1701) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The Air Cell Massager stimulates 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.	Similar
Treatment area/Structure of Sleeves	Low limbs (Foot, calf and upper leg)	Low limbs (Foot, calf and upper leg)	Same
OTC or Rx	OTC	OTC	
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	
Power source	100-127Vac 50/60Hz	100~240V 50/60Hz	Similar
Power Consumption	480VA	12W	Different (Note 2)

SW/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Same
Output pressure range	48~240 mmHg	0~240 mmHg	
Air pressure level/Compression levels	9 levels settings: Level 1 : 48mmHg Level 2 : 72mmHg Level 3 : 96mmHg Level 4 : 120mmHg Level 5 : 144mmHg Level 6 : 168mmHg Level 7 : 192mmHg Level 8 : 216mmHg Level 9 : 240mmHg	3 levels settings: low level: 150mmHg, Mid-level: 185mmHg, High Level: 215mmHg (± 25mmHg)	Different (Note 3)
Mode types	Sequential/ Peristaltic	Sequential/ Peristaltic	Same
Inflation time	1min~1min 30s	3-30s	Different (Note 4)
Therapy Time	18 minutes	20 minutes	
Keep time	1~13s	1-5s	
Deflation time	1~10s	1-5s	
Cycle time	Range of 28 sec to 39sec	Range of 25 sec to 3 min 40 sec	
Number of chambers	4 Chambers	3 Chambers	
Number of treatment mode	3 modes	3 modes	Same
Modes (visual description)	 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	**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. Mode 1 follows	Different (Note 5)

	decompresses and the 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 four sections then decompress simultaneously, and the air pressure drops, then cycle begins again. Mode 3: Start between the foot chamber to the thigh chamber except for No. 4 chamber. And No.4 chamber is compressed while the other chambers are maintained. After that all four sections decompress simultaneously and the air pressure drops, then cycle begins again. This sequence is similar to the Mode 2.	this pressure sequence:  **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 begin again. Mode 2 follows this pressure sequence:  **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 ⇄ Mode 2	

		The pressure sequence of mode 3 combines mode 1 and mode 2	
Sleeve Material	Oxford and Nylon	Nylon with a Polyurethane laminate	Similar
Patient contact	Non-conductive attachments	Non-conductive attachments	Same
Size and appearance of sleeves (leg part)	Leg:  One size：28*58.4cm	Leg:  One size：73*26cm	Different (Note 6)
Safety Features	Power On/off and mode start/pause button allows user to stop therapy session at any time	Standby button allows user to stop therapy session at any time	
Transportation & Storage environment	Temperature: -20℃ to 60℃ Humidity: 10% to 95% Atmospheric pressure: 500hPa -1060hPa	Temperature: -20℃~55℃ Humidity: 5%-90% noncondensing Atmospheric Pressure:75kPa ~ 106kPa	
Standards	ANSI AAMI ES60601-1:2005/®2012 and A1:2012, C1:2009/®2012 IEC 60601-1-2 Edition 4.0 IEC 60601-1-6 Edition 3.1 IEC 60601-1-11 Edition 2.0 ISO 10993-5 Third edition ISO 10993-10 Third Edition	ES 60601-1; IEC60601-1-2; ISO 10993-5: ISO 10993-10; IEC 60601-1-11	

Substantial Equivalence Discussion

The subject device is an upgraded version of the predicate device that features "Air Cell Massage" which allows users to stimulate leg tissues by kneading and stroking by wearing an inflatable garment. The key differences of the two devices are:

Note 1: The design change is simply an exterior change that does not impact the efficacy or safety of the device.

Note 2: Although the "power consumption" of the subject device is different than the predicate devices, they both use a power adaptor and the adaptor both comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness

Note 3:
The air pressure/compression levels of the subject are divided into 9 levels whereas the predicate device's air pressure levels are divided into 3 levels. The minimum pressure level of the subject is significantly lower than the predicate and the maximum pressure level is same as the predicates, so there is no safety issue concerned and as for the efficacy, it remains valid since its performance has been demonstrated by the performance testing data included in this submission.

Note 4:

- Inflation time: Inflation times are slightly different but there are no safety or efficacy issues because it just requires more time to inflate one more chamber.
- Therapy Time: Therapy time of subject device is 2 minutes less than the predicate's and such difference does not raise any safety or efficacy issues.
- Keep time: Keep times are slightly different but there are no safety or efficacy issues because it just requires more time to keep on for one more chamber.
- Deflation time: Deflation times are slightly different but there are no safety or efficacy issues because it just requires more time to deflate one more chamber.
- Cycle time: Although the cycle time of subject device is different the predicate devices, but the range of cycle time falls under the predicate's, so such difference does not affect the safety and effectiveness.
- Number of chambers: Although the number of chambers of subject device is different to the predicated device (one more chamber for subject device), 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 5: While both devices are comprised of three modes of treating for the same treatment areas - foot, calve and thigh, - the only difference is the sequence in which the air pressure is provided to each treatment area. Therefore, there are no significant efficacy or safety issues raised.

Note 6:

- Size and appearance of sleeves (leg part): Slight differences of size and appearance of the sleeves do not raise any safety or efficacy issues.
- Safety Features: They are just different types of the features, and both will be effective to function as safety features, thus such difference does not raise any safety or efficacy issues.
- Transportation & Storage environment: Such difference does not raise any safety or efficacy issues.
- Standards: Such difference does not raise any safety or efficacy issues.

The subject device has same intended use, principle of operation, and technological characteristics as the predicate devices. Although there are several specifications that are different between the two devices, testing and discussion been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results conformed with the test requests. Therefore, the differences between the subject device and the predicate devices do not raise any concerns with respect to substantial equivalence.

Non-Clinical Test Data

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

- Skin Temperature Study
- The usability study was performed to validate that the lay users can use the subject device only with the User Manual provided.
- The EMC and electrical safety testing were conducted on the subject device in accordance with ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-1-11 to demonstrate the safety and effectiveness.
- The level of concern for the subject device's software is *moderate* and the validation tests were performed to verify that the firmware works as intended. The test results support that the subject device is substantially equivalent to the predicate device.
- Biocompatibility studies were performed to evaluate the safety of the new materials which comes in contact with the patients in accordance with the FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" issued in 2016 and ISO 10993 standards as follows, and the results satisfied the ISO standards requirements.
  - Cytotoxicity Test per ISO 10993-5:2009
  - Sensitization per ISO 10993-10:2010
  - Irritation Test per ISO 10993-10:2010

Electrical safety and electromagnetic compatibility (EMC)
The EMC and electrical safety testing were conducted on the subject device in accordance with the following standards.

- ANSI AAMI ES60601-1:2005/®2012 and A1:2012, C1:2009/®2012
- IEC 60601-1-2 Edition 4.0
- IEC 60601-1-6 Edition 3.1
- IEC 60601-1-11 Edition 2.0

- ISO 10993-5 Third edition
- ISO 10993-10 Third Edition

Software Verification and Validation Testing

Software validation activities have been conducted and the reports were prepared in accordance with "FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices". The level of concern was determined "Moderate".

Conclusions

The subject device is substantially equivalent in intended use, technological characteristics/ principles of operation, materials, and performance to the predicate device and the differences between the subject and predicate devices do not raise new questions of safety and effectiveness.