March 2, 2021

Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K202113
Trade/Device Name: Ceragem Automatic Thermal Massager, Model CGM-MB-1901
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-Function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB
Dated: December 14, 2020
Received: December 21, 2020

Dear Priscilla Chung:

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,

Jitendra Virani
Acting 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)*
K202113

Device Name
Ceragem Automatic Thermal Massager, Model CGM-MB-1901

Indications for Use *(Describe)*
The intended use of the Ceragem Automatic Thermal Massager, Model CGM-MB-1901 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

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

(K202113)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Feb 18, 2020

1. 510K Applicant / Submitter:

CERAGEM Co, Ltd.
10, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu,
Cheonan-si, Chungcheongnam-do
31041 Republic of Korea

2. Submission Contact Person

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3. Device

- Proprietary Name: Ceragem Automatic Thermal Massager, Model CGM-MB-1901
- Regulation Number: 21 CFR 890.5880
- Regulation Name: Multi-Function Physical Therapy Table
- Regulatory Class: Class II
- Product Code: JFB

4. Predicate Device

Automatic Thermal Massager, Model CGM MB-1101 (K140592) by Ceragem International, Inc.

5. Description:

The Ceragem Automatic Thermal Massager, Model CGM-MB-1901 is an electrically powered, motorized, multi-functional physical therapy table intended to use for temporary

relief of muscle/joint pain and stiffness by applying massage pressure from the vertical and horizontal movements, and heat from the internal and external projectors.

The main components of the subject device are a main mat, a supporting mat, a 3-Sphere projector, an abdominal vibration projector, and a remote control. The main mat has an internal projector which includes an up/down movement motor for pressure effect with ceramic balls as a medium for thermal massage effect. The internal projector is located in the center of the mat which is mainly for spine and moves up and down as well as vertically. The main mat also has a heating pad. The supporting mat which is mainly for the legs have heating pad only.

The 3-sphere projector is an optional accessory which the user can put anywhere needed additionally such as neck and armpit, and it has 3 balls for thermal effect. The abdominal vibration projector is also an optional accessory mainly for abdominal area and offers vibration and thermal effect.

8. Indications for Use

The intended use of the Ceragem Automatic Thermal Massager, Model CGM-MB-1901 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

9. Substantial Equivalence Discussion:

9.1. Comparison Chart

	Subject Device	Predicate Device
Device Name	CGM MB-1901 Automatic Thermal Massager	CGM MB-1101 Automatic Thermal Massager
Manufacturer	CERAGEM Co, Ltd.	CERAGEM Co, Ltd.
510(k) Number	K202113	K140592
Rated Voltage	100-127Vac 50/60Hz	100-127Vac 50/60Hz
Home Use	Yes	Yes
Style	Flood Model (Massage Bed)	Flood Model (Massage Bed)
Components	Main Mat	Main Mat
	Supporting Mat	Lower Mat
	Remote Control	Remote Control
	3-Sphere projector	3-Sphere projector
	Abdominal Vibration Projector	9-Sphere projector
	Power cord	Power cord
	Outer fabric	Outer fabric
	Head cushion	Head cushion
	Projector Cover	Projector Cover

Remote Control		Yes	Yes
Operation Method		Auto / Manual	Auto / Manual
Infrared Emission Spectrum		Ceramic : 5~20㎛ Epoxy Carbon Panel : 5~20 ㎛	Jade : 5~20㎛ Epoxy Carbon Panel : 5~20 ㎛
Heating Device	Voltage	24V	24V
	Power	18W	15W
Temperature Range		1. Internal: 30℃ - 65℃ (86℉ - 149℉) 2. External, Main, Auxiliary: 30℃ - 60℃(86℉ - 140℉)	1. Internal: 30℃ - 65℃ (86℉ - 149℉) 2. External, Main, Auxiliary: 30℃ - 60℃(86℉ - 140℉)
Distance of the Internal Projector		710mm	710mm
Intensity Level		1~9 (21~75mm)	1~6 (21~75mm)
Extra Overheating Protection		Yes	Yes
Moving Device		Geared DC Motor	Geared DC Motor
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 Cover	Nylon Polyurethane	Polyethylene
Projectors	Internal Projector	1 Ceramic Ball in the Middle 4 Ceramic Rollers(Total of 5)	1 Jade Ball in the Middle 4 Jade Rollers(Total of 5)
	External Projectors	Three (3) Ceramic Heads Projector Nine (9) Ceramic Heads Projector	Three (3) Jade Heads Projector Nine (9) Jade Heads Projector
Mat Dimensions		1.When spread out : 700mmx2040mmx450mm(±5mm) 2.When folded : 700mmx1250mmx450mm(±5mm)	1.When spread out : 700mmx2016mmx450mm(±5mm) 2.When folded : 700mmx1258mmx450mm(±5mm)
Weight		Main/Supporting body : 52kg(±2kg)	Main body : 23kg(±2kg) Sliding support : 14kg(±2kg) Frame : 16kg(±2kg)
Mode		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	Semi-Automatic Mode
		Mode 10	Manual Mode
		Mode 11	
		Intensive Mode	

	Semi-Automatic Mode	
	Semi-Automatic Master Mode	
	Manual Mode	
	Manual Master Mode	
	Abdominal Vibration Projector Mode	

9.2. Substantial Equivalence Discussion

The subject device is similar to the predicate device in the indications for use, principle of operation, and technological characteristics. The performance specifications are nearly the same, yet the subject device has more choosing options. For example, the intensity level specification is the same between the subject device and the predicate device, but the subject device divided the range into 9 options instead of 6 to better meet user's intensity preferences. The same thing applies to the massage mode that the overall massage specification is the same, but the subject device offers more variety of the massage patterns and options.
The major difference is the material of the internal heating element has changed. We have performed the skin temperature to validate the performance of the heating massage and the test results support that the subject device is substantially equivalent to the predicate device.
Another difference is that the subject device has upgraded the 9-Sphere projector to have vibration feature for massage effect. So, we have changed the term for this component to Abdominal Vibration Projector. This vibration function is just an additional feature and still the main function of this projector is heating. The skin temperature test result supported that the Abdominal Vibration Projector performs as well as the predicate device. Similar to the predicate device, the subject device was able to heat skin to 40-45 degree C within 15-20 minutes. During the intended treatment the subject device maintained skin temperature between 40-45 degree C.

10. Performance Tests (Non-clinical)

- The skin temperature study was performed to verify that the subject device maintained skin temperature between 40-45 degree C during the intended treatment.
- 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.
- The cytotoxicity test per ISO 10993-5 and skin irritation & sensitization tests per ISO 10993-10 were performed to evaluate the safety of the new materials which contact the patients.
- The level of concern for the subject device SW is moderate and the validation tests were performed to verify that the firmware works as intended.

The test results of all the tests supported that it is substantially equivalent to the predicate

device.

11. Conclusions:

Based on the information provided in this premarket notification, CERAGEM Co, Ltd. concludes that the Ceragem Automatic Thermal Massager, Model CGM-MB-1901 is substantially equivalent to the predicate device as described herein in.