

JUL 28 2004

XI. 510(k) SUMMARY

Pursuant to 513(i)(3)(A) of the Food, Drug and Cosmetic Act, Ceragem Co., Ltd is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Ceragem Co., Ltd. chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Submitter's Name

CERAGEM Co., Ltd

177-14, Osaejdabg-ri, Seongger-eup, Cheonan-si,

Chungcheongnam-do, Korea

President, Masoon, Kwang Park

Tel: 273-426-7151

Date Prepared:

December 31, 2003

Proprietary Name:

CERAGEM-C Thermal Massager

Classification Name:

Multi-Function Therapy Table (Class II), 21 CFR 890.5880

Predicate Device:

Migun HY5000 Thermassage Energy Product (K032449)
Migun Medical Instrument Co., Ltd.

Product Description:

The **CERAGEM-C Thermal Massager** is an electrically powered motorized multi-functional physical therapy table. Its intended use is to provide muscle relaxation therapy by delivering heat and soothing massage. The massage function is delivered by massage rollers mounted on an independent carriage underneath a pad on the table torso section. The heat function is delivered by two components (1) heated jade massage rollers mounted together on the moving carriage and (2) heated Epoxy Carbon Panels. In both cases, **the radiant infrared heat is emitted**. Together, the massage action and heated pressure points apply light pressure as well as **radiant infrared heat** to the user.

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Statement of Intended Use Compared to Predicate Device:

The intended use of the CERAGEM-C Thermal Massager is the same as the above-identified predicate device. It is intended to provide muscle relaxation therapy by delivering heat and soothing massage.

Additionally, the CERAGEM-C Thermal Massager provides radiant infrared heat for:

- ◇ temporary relief of minor muscle and joint pain, and stiffness
- ◇ the temporary relief of minor joint pain associated with arthritis
- ◇ the temporary increase in local circulation where applied
- ◇ relaxation of muscles

Discussion of Technological Characteristics:

Both the CERAGEM-C Thermal Massager and the predicate device use massage rollers and heat to provide muscle relaxation therapy. The CERAGEM-C emits topical radiant infrared heat in the range of 5-20 microns from the jade massage rollers, heated by light bulbs located inside the rollers. The predicate device also emits topical heat through light bulbs located in the jade massage rollers in the range of 5-20 microns. Both the CERAGEM-C device and the predicate provide the massage component by attaching the jade rollers to a carriage mounted under a padded cushion that traverses the torso. The CERAGEM-C device also transmits heat through the three Epoxy Carbon Panels. While the predicate device does not include Epoxy Carbon Panels, the maximal heat of the CERAGEM-C remains lower than that of the predicate. Additionally, both the CERAGEM-C and the predicate device have been tested to and meet the following standards:

1. Underwriters Laboratories Standard UL 60601-1:1997 2nd Edition, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments 1 and 2;
2. CAN/CSA C22.2 No. 601.1-M90, "Medical Equipment Part 1: General Requirements for Safety," including C22.2 No. 601.1 S1-94, Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90.
3. EN 60601-1 (1990), "Medical Electrical Equipment Part 1, General Requirements for Safety" including Amendments A1 and A2;
4. IEC 60601-1, 2nd Edition (1998) "Medical Equipment- General Requirements for Safety + A1:91 and A2:95"; and
5. IEC 60601-2-38, 1st Edition (1996) "Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Electrically Operated Beds."



Conclusion:

Based on comparison of the CERAGEM-C Thermal Massager to the predicate device, we conclude that the CERAGEM-C Thermal Massager has the same intended use, indications for use, and intended population, and similar functional and performance characteristics. The addition of the three Epoxy Carbon Panels does not raise new safety or effectiveness issues since the temperature never exceeds the maximal temperature of the predicate device. Other visual distinctions do not impact safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2004

Ceragem Company, Ltd.
c/o Ms. Suzan Onel
Kirkpatrick and Lockhart LLP
1800 Massachusetts Avenue, NW
Suite 200
Washington, DC 20036

Re: K040031

Trade/Device Name: Ceragem-C Thermal Massager
Regulation Number: 21 CFR 890.5880
Regulation Names: Multi-function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB
Dated: April 28, 2004
Received: April 29, 2004

Dear Ms. Suzan Onel:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

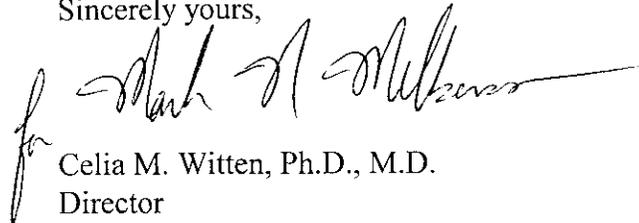
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594- 1308. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Page ___ of ___

510(k) Number (if known): _____

Device Name: CERAGEM-C Thermal Massager

Indications For Use:

The intended use of the CERAGEM-C Thermal Massager is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the Ceragem-C Thermal Massager provides radiant infrared heat for:

- ◇ temporary relief of minor muscle and joint pain, and stiffness
- ◇ the temporary relief of minor joint pain associated with arthritis
- ◇ the temporary increase in local circulation where applied
- ◇ relaxation of muscles

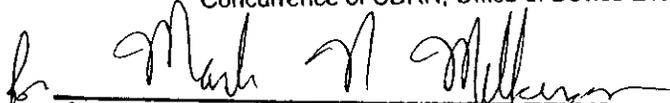
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

(Optional Format 3-10-98)

510(k) Number K040031