K070672

## 10. 510(k) SUMMARY

JUN 26 2007

Pursuant to 513(i)(3)(a) of the Food, Drug and Cosmetic Act, Metek GmbH is required with this pre-market notification to provide either "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request by any person. Metek GmbH chose to submit a summary of the safety and effectiveness information. The summary is as follows:

| | |
|---|---|
| Submitter's name: | Metek GmbH<br>Stammweg 8<br>37327 Leinefelde<br>GERMANY |
| Date prepared: | November, 15th, 2006 |
| Proprietary Name: | MASSAGE MATTRESS VM9100RM |
| Classification Name: | Multi-Function Therapy Table (Class II),<br>21 CFR 890.5880 |
| Predicate Device | CERAGEM-C Thermal Massager (K K040031)<br>Ceragem Company Ltd., Kirkpatrick and Lockhardt LLP, 1800 Massachusetts Avenue, NW<br>Washington, DC 20036 |

Product description:

The MASSAGE MATTRESS VM9100RM is an electrically powered motorized multi-functional physical therapy mattress. It is intended to provide muscle relaxation therapy by delivering heat and soothing massage. The massage function is delivered by oscillating motors that are embedded in the mattress body. The heat function is delivered by two components (1) a back pad and (2) a calf pad both containing a heating panel. In both cases, radiant infrared heat is emitted. Both, the oscillating function and the heated pressure apply light pressure as well as radiate infrared heat to the user.

Discussion of Technological Characteristics:

Both, the MASSAGE MATTRESS VM9100RM and the predicate device provide massage and heat to muscle relaxation therapy. The MASSAGE MATTRESS VM9100RM does not use jade rollers to provide the massage function as the predicate operates with. Instead it uses oscillating motors to deliver vibrations to

the user. The predicate devices also emits heat through EPOXY CARBON PANELS, whereas the MASSAGE MATTRESS VM9100RM uses only two panels, located in two pads. While the predicate device uses direct power supply, the MASSAGE MATTRESS VM9100RM uses indirect, safety low-voltage power. It is supplied by a power circuit.

Standards tested

The standards tested are
- EN 60601-1; 1990 A1
- EN 60601-1: 1990 A2

In case there is a need to use another power circuit supplied, this was tested according to the standards
- EN 60601-1:1990
- EN 60601-1:1993 A1
- EN 60601-1:1993 A2

The AC power adapter used was tested according to the standards
- EN 50076:1990 and
- EN 60320-1: 1996 + A1 + A2

The Certificates No. 60009868, 2156443, and the Test Report No. 21123617_001 are attached to the 510(k).

The product as a complete product was tested according to the standard
- BS EN 597-2: 1994

The Test Report No.21129516001 are attached to the 510(k).

The device is intended:

To provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the radiant infrared heat provides topical heating for:
- the 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
- muscle relaxation

The device is easy and safe to use and can therefore be used in hospitals as well as at home and in gymnasiums. There is no recommendation or restriction on how often the device should be used in order to treat the symptoms described.
The MASSAGE BED VM9100RM has been produced for over-the-counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Metek GmbH
% Tamas Borsai
TÜV Rheinland
12 Commerce Road
Newton, Connecticut 06470

JUN 26 2007

Re: K070672
Trade Name: Massage Mattress VM9100RM
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB
Dated: June 13, 2007
Received: June 15, 2007

Dear Mr. Borsai:

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.

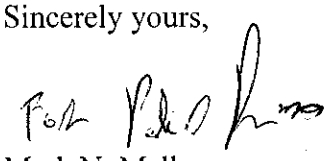
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# 1. INDICATION FOR USE

Device name: MASSAGE MATTRESS VM9100RM

The device is intended:

To provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the radiant infrared heat provides topical heating for:

- the 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
- muscle relaxation

The device is easy and safe to use and can therefore be used in hospitals as well as at home and in gymnasiums.
The MASSAGE BED VM9100RM has been produced for over-the-counter use.

**(Division Sign-Off)**
**Division of General, Restorative and Neurological Devices**

**510(k) Number** K040672

Prescription Use_____ AND/OR Over-The-Counter Use___X____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device evaluation