MAY 01 2002

K011859

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Klimamed® Technologie Medizingeräte GmbH
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Herrenberg GERMANY
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5-Contact Person: Thomas Schneider, quality inspector
6-Date summary prepared: May 30th, 2001
7- Official Correspondent: Mansour Consulting
8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
9- Phone: (678) 429-8180
10- Fax (425) 795- 9341
11- Contact person: Jay Mansour, president
12-Device Trade or Proprietary Name: Klimamed® Thermal Mat & Controller 95 & 55 Watts
13-Device Common or usual name: Thermal mat and controller
14-Device Classification Name: System, Thermal regulating
15-Substantial Equivalency is claimed against the following device:

- Allon 2001 by M.T.R.E Advanced Technology, Ltd (refer to appendix 2)

16-Description of the Device:

DESCRIPTION/INDICATION FOR USE by physicians in clinics and hospitals

This device is an external thermal regulating system consisting of a mat that is placed in contact with the patient and a temperature controller and is to regulate the patient's temperature between 30 and 37.7 °C (86 and 100°F), using carbon technology

The heating element and sensor are both embedded inside the mat. Two mat sizes are available:

1- 95 Watts, Standard 0.950 by 0.495 meters (3.1 by 1.6 ft) and 9mm high (0.35 inches) weighing 5 kg (11 lbs) (Product code 75/95/12M) for adult patients
2- 55 Watts, Pediatric 0.550 by 0.495 meters (1.8 by 1.6 ft) and 9mm high (0.35 inches) weighing 3.5 kg (7.7 lbs) (Product code 55/95/12M) for pediatric patients

75/95/12PRM consists of the Controller Micro 75-150 (product code 120/240/12PM) and mat 75/95/12M
55/95/12PRM consists of the Controller Micro 75-150 (product code 120/240/12PM) and mat 55/95/12M

The device is intended to maintain pre-set body temperature as determined by the physician. It can also be utilized to maintain normal body temperature during surgical procedures. It is indicated for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors

17-Intended use of the device:

The device is intended to maintain pre-set body temperature as determined by the physician. It can also be utilized to maintain normal body temperature during surgical procedures. It is indicated for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors

18-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 19 below)

19-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that **Klimamed® mat & controller** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency detailed chart path is attached.

REFER TO PAGES 9 AND 10 FOR DETAILED INFORMATION

FDA file reference number	510k K001546
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Similar
Thermal safety	Similar
Radiation safety	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 01 2002

Klimamed® Technologie Medizingeräte GmbH
c/o Mr. Jay Mansour
President
Mansour Consulting
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: K011859
Trade Name: Klimamed® Thermal Mat & Controller 95 & 55 Watts
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: January 21, 2002
Received: January 31, 2002

Dear Mr. Mansour:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011859

Device Name: THERMAL MAT & CONTROLLER (REF. 75/95/12PRM & 55/95/12PRM)

Indications For Use:

THIS DEVICE IS INDICATED TO MAINTAIN PRE-SET BODY TEMPERATURE AS DETERMINED BY THE PHYSICIAN.
IT CAN ALSO BE UTILIZED TO MAINTAIN NORMAL BODY TEMPERATURE DURING SURGICAL PROCEDURES.
IT IS INDICATED FOR USE IN HOSPITAL INVASIVE AND CORONARY CARE UNITS, IN OPERATING, RECOVERY AND EMERGENCY ROOMS, IN BURN UNITS, AND ON MEDICAL / SURGICAL FLOORS

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011859

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)