JUN 2 2 2004

K040911

Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3

Dynatherm Medical, Inc.	Phone: (650) 777-4361 Fax: (650) 777-4370
Official Contact:	Nathan Hamilton
Proprietary or Trade Name:	VitalHeat™
Commom/Usual Name:	VitalHeat™
Classification Name:	Thermal Regulating System
Predicate Device:	Aquarius Medical Corporation Thermo-STAT – K970367 Aquarius Medical Corporation AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

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Indicated Used:

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

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Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

2.1 Summary of Safety and Effectiveness

510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size - Controller	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes – Water Flow	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	Yes	Yes	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

Dynatherm Medical, Inc.
c/o Mr. Nathan Hamilton
819 Mitten Road, Suite 42
Burlingame, CA 94010

Re: K040911
VitalHeat™
Regulation Number: 21 CFR 870.5906
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: June 3, 2004
Received: June 7, 2004

Dear Mr. Hamilton:

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) 594-4646. 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,

Donna R Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040911

Device Name: VitalHeat™

Indications For Use:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number: K040911