

AUG 29 1997

K964799

ATTACHMENT III

**REVISED
SUMMARY OF SAFETY AND
EFFECTIVENESS INFORMATION**

14964799

Section 510(k) Premarket Notification
Summary of Safety and Effectiveness Information

For the ORMED, GMBH - ARTROTHERM™
CRYOTHERAPY AND THERMOTHERAPY UNIT

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: **ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY**

Common Name: **Water Circulating Hot or Cold Pack**

Classification Name: **Water Circulating Hot or Cold Pack**

3. Establishment Name & Registration Number:

Name: **ORMED, GMBH**

Number: **2247872**

4. Classification:

§ 890.5720 Water circulating hot or cold pack. (a) Identification. A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces. (b) Classification. Class II (performance standards).

Product Code: **89ILO**

Device Class: **Class II**

Classification Panel: **Physical Medicine**

5. Contact Person:

Mrs. Margit Bayha
ORMED, GMBH
Merzhauser Strasse 112
D-79100 Freiberg I. B.
Germany
011 49 7 61/45 84 471 (voice)
011 49 7 61/45 84 450 (fax)

6. Special Controls:

Special controls have not been established for this device.

7. Device Description:

Intended Use: Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and or surgical conditions.

Indications for Use: 1) Treatment of pain and swelling of acute periarticular processes. 2) Treatment of pain and swelling following mobilization of shoulder stiffness under anesthesia. 3) Treatment of pain and swelling postoperatively for bones, joints and soft tissue. 4) Treatment of pain and swelling caused by musculoskeletal contusions and athletic injury.

Background: The **ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY** like the referenced equivalent devices, is a typical thermal therapy device. As a group, thermal therapy devices are capable of producing both heating and cooling effects depending on the therapy mode selected. Thus, it is possible to administer hot or cold therapy or hot & cold therapy in alternating fashion without removal and reapplication of different pieces of equipment.

Typical thermal therapy units consist of a compact heating and chilling unit equipped with a liquid circulating electric pump. The pump circulates a liquid (usually water or a water/alcohol mixture) around the heating/cooling elements or heat exchanger of the thermal therapy device. The heated or cooled liquid is then circulated to the treatment site via insulated tubing to a patient contact pad or cuff. Placement straps or wraps are used to hold the cuff/pad in place during treatment. Frequently, standard elastic wraps (Ace-type bandages) are used to hold the cuff/pad in place.

Following the fashion of available devices, the **ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY** unit also utilizes a small portable heating and cooling unit, a length of dual lumen connecting tubing and assorted thermal therapy cuffs/pads. The various cuff/pads of the **ARTROTHERM™** are shaped to better contour to different body surfaces.

Therapy pads designed to accommodate the ankle, foot, wrist, hand, back, shoulder, hip, neck and knee are offered at present. The pads are held in place with straps and/or wraps.

Basic Operation: For the first set-up, the cap of the fluid reservoir is removed and a 4:1 solution of water and alcohol is poured into the unit. A premixed alcohol/water solution is available for use with the unit. With the pump running and the connecting tubing and cuff attached, the alcohol/water solution is poured in until the reservoir no longer pumps dry. When the air bubbles have been purged from the system, the reservoir will be about 3/4 full. Replace the fluid reservoir cap tightly, the unit is now ready for service. The cuff and tubing are equipped with sealing connectors and will remain filled after the initial set-up application. A few drops of fluid may escape when the cuff/tubing are disconnected, this is normal. Additional fluid is added to the reservoir whenever a new empty cuff is attached to the system for the first time.

The unit requires 110 -115 or 220-230 VAC 50/50Hz current for operation. The unit is fully electrically isolated and meets UL-544 requirements. The ground leakage current value for the water circulating electric pump is less than 55 micro-amps.

Minimum and maximum cooling and heating temperatures are affected by available environmental conditions, size of pad selected and patient temperature. Under typical conditions, best low temperature is +4 °C. Best low temperature is achieved after approximately 30 minutes of operation. Maximum high temperature is +50 °C and the unit requires about 15 minutes to reach this level. The heating cycle is generally less affected by environmental conditions.

A high temperature alarm is utilized to warn of temperatures in excess of the +50 °C. There is no automatic high temp system shut off, the device is to be shut off and removed by the patient or operator when the high temperature alarm sounds.

8. Substantially Equivalent Device(s):

The **ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY** is substantially equivalent to the following devices:

1. **TTU-100** by Danninger Medical Technology, Inc.
2. **Hot/Ice® HE500/A** by ThermoTemp, Inc.

9. Comparison to Predicate Device(s):

Two currently available thermal therapy devices have been selected for comparison with the **ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY**. The first is the **TTU-100 Thermal Therapy Unit** from Danninger Medical Technology, Inc. The second device is called the **Hot/Ice® HE500/A** made by ThermoTemp, Inc.

Minimum and maximum operation temperatures are 35° and 116° F. for the TTU-100 and 40° to 105° F. for the Hot/Ice unit. These temperature ranges compare equivalently to the **ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY** unit temperature range of 43° to 122° F. The intended use of all three units are the same. All devices provide localized heating or cooling therapy to selected body surfaces. Hot or cold therapy is useful in treating various traumatic or surgical conditions related to orthopaedics, sports medicine, rheumatology, general surgery, plastic surgery, reconstructive surgery, chirosurgery, foot surgery and selected neurology conditions.

Water temperature control is accomplished by rheostat in the **ARTROTHERM™** device and by digital controls in both of the comparison devices. This slight difference in temperature control mechanism is unimportant because either control is adequate. Water temp display is digital for all three devices utilizing either LCD or LED display characters.

All three units function on standard electrical outlet current of 120 VAC 60 Hz, though both the **ARTROTHERM™** and the **Hot/Ice® HE500/A** units will operate on 220-230 VAC 50/60 Hz current as well. All three units meet UL-544 requirements for electrical safety. All three units are grounded, safety fused and overload protected. The ground leakage current value for the **ARTROTHERM™** and the comparison units is less than 55 micro-amps.

The weight of all three units is essentially the same, being 21, 23 and 22 pounds respectively.

The circulating heat transfer fluid for the units is equivalent. A water alcohol mixture is used in the **ARTROTHERM™** (80%-20%) and the **Hot/Ice® HE500/A** (70%-30%) units while only distilled water is used in the **TTU-100 Thermal Therapy** unit. The **TTU-100 Thermal Therapy** unit uses a water alcohol mixture for cleaning and maintenance.

10. Packaging:

Standard, paper fiber industry typical bulk shipper packaging is utilized. The packaging selected for use is sufficient to identify, protect and transport the device safely.

11. Sterilization/Re-sterilization:

The device may not be sterilized or re-sterilized. Surface disinfecting is possible using commercially available non-solvent based disinfectant products. Cleaning and sanitizing instructions are supplied with each ARTROTHERM™ unit.

12. Conclusion:

Based on the materials, intended uses, design, and effectiveness, the ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY unit is equivalent to the referenced legally marketed comparison water circulating cold packs. The feature comparison chart below graphically demonstrates this equivalence.

13. Comparison Table:

FEATURE	ARTROTHERM™	TTU-100	Hot/Ice®	SE?
Intended Use:	Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and or surgical conditions.	Same	Same	Yes
Cuff:	5 styles/sizes	3 styles/sizes	5 styles/sizes	Yes
Water Temp Control:	Rheostat	Digital	Digital	Yes
Water Temp Indicator:	LCD	LCD	LED	Yes
Temperature Range(s):	43°F to 122°F, user selectable	35°F -116°F user selectable in 1° increments	40°F -105°F user selectable in 1° increments	Yes
Electrical Requirements:	110 -120 VAC 50/60 Hz 220-230 VAC 50 Hz	120 VAC 60 Hz	115 VAC 50/60 Hz 230 VAC 50/60 Hz	Yes
Ground Leakage Current Value:	<55 micro-amps	<55 micro-amps	<55 micro-amps	Yes
Weight:	22 lb.	23 lb.	21 lb.	Yes
Recirculating Fluid:	Water/alcohol, 80%/20% mixture	Distilled water, water/alcohol mix for cleaning and maintenance only	Water/alcohol mix 70%/30%	Yes
Performance Standards:	UL/ETL compliant	UL/ETL compliant	UL/ETL compliant	Yes
Disposable cuff covers:	Yes	Yes	Yes	
Safety:	Grounded, fused & overload protected Auditory alarm - water for temp above 122°F	Automatic shutoff above 116°F or below 35°F water outlet temperature, Low water level or unit tilt greater than 45°	Low fluid, no- fluid flow , high/low temperature extreme and blocked air flow indicator lights	Yes
Manufacturer:	Medireha	Danninger	ThermoTemp, Inc.	Yes



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David W. Schlerf
Buckman Company, Inc.
Representing Ormed, GmbH
1000 Burnett Avenue, Suite 450
Concord, California 94520

Re: K964354
Artrocool®-S Water Circulating Cold Pack
K964799
Artrotherm™ Cryotherapy and Thermotherapy
Regulatory Class: II
Product Code: ILO
Dated: July 27, 1997
Received: July 29, 1997

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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.

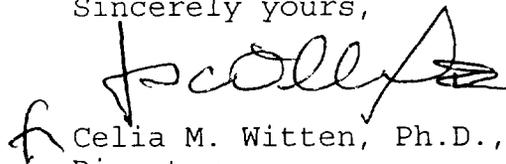
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your pre-market notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): _____

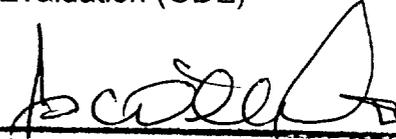
Device Name: ARTROTHERM™ CRYOTHERAPY AND THERMOTHERAPY

Indications For Use:

1. Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Director Sign-Off)
 Division of General Restorative Devices
 510(k) Number K 964 799

Prescription Use _____

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional format 1-2-96)