AUG 29 1996

K964354

ATTACHMENT III

REVISED
SUMMARY OF SAFETY AND
EFFECTIVENESS INFORMATION

K964354

Section 510(k) Premarket Notification **Summary of Safety and Effectiveness Information**
ORMED, GmBH

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

1. **Device Trade Name:** **Artrocool®-S** Water Circulating Cold Pack

2. **Common Name:** Water Circulating Cold Pack

   Classification Name: Water Circulating Cold Pack

3. **Establishment Name & Registration Number:**

   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)

   Reg. 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:

The **Artrocool®- S** is a typical cold liquid recirculating cryotherapy device. The **Artrocool®-S** is an insulated ice chest-like box with a closed loop liquid recirculating pump and tubing. The tubing connects to a variety of cuffs designed to be placed on or around injured or post surgical body structures, limbs or joints. The device operates by the use of a water filled cartridge and an insulated chest. The water filled bottle is frozen solid prior to first use. When the bottle is frozen, it is placed within the insulated chamber of the Artrocool. A 4:1 mixture of water and alcohol is poured into the fluid reservoir (balancing container) until full. The pump is circulated with the connecting tubing and cuff attached. Once both are filled and all air bubbles have been purged from the system the unit is ready for service.

8. Substantially Equivalent Device(s):

The **Artrocool®-S** is substantially equivalent to the **Theracool™** Water Circulating Cold Pack, the **Polar Care™** Water Circulating Cold Pack, the **Dr. Kool™** Water Circulating Cold Pack and the **Cryo Cuff™** Water Circulating Cold Pack.

9. Comparison to Predicate Device(s):

With the exception of the **Cryo Cuff™** which is a gravity flow device, the **Artrocool®-S** and the remaining cold therapy units utilize a small DC electric pump to circulate and recirculate a chilled fluid through an assortment of body contact pads or cuffs. All of the powered units including the **Artrocool®-S** are UL-544 compliant. The water circulating electric pump has a ground current leakage value of less than 55 micro-amps.

None of the units depend on direct refrigeration of the circulating liquid. The **Dr. Kool™** and the **Artrocool®-S** utilize a container of frozen water or chemical gel to cool the isolated recirculating liquid. The rest of the units circulate melt water throughout the system.

The intended uses of all of the units are essentially the same and include conditions like trauma, orthopaedic surgery, sports medicine injuries and rehabilitation, rheumatology, general, plastic and reconstructive surgery, chirosurgery and neurology. All the devices are suitable for any traumatic, medical or surgical conditions benefiting from cold therapy.

The duration of therapeutic cold conditions for all of the units is variable depending on issues like pad/cuff size, ambient temperature, patient temperature, etc. Time duration of useful cold therapy for the comparison units is from 1 ½ to 10 hours. The **Artrocool®-S** provides cooling for 6 to 8 hours of continuous use..

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:

May not be sterilized or re-sterilized. Surface disinfection is possible using commercially available non-solvent based disinfectant products. Cleaning and sanitizing instructions are supplied with each **Artrocool®-S** unit.

12. Conclusion:

Based on the materials, intended uses, design, and effectiveness, the **Artrocool®-S** Water Circulating Cold Pack is equivalent to the referenced legally marketed comparison water circulating cold packs. The feature comparison chart below graphically demonstrates this equivalence.

13. Feature Comparison Table:

FEATURE	Artrocool®	Theracool™	Polar Care™	Dr. Kool™	Cryo Cuff™	SE?
Intended Use	Trauma, orthopaedics, sports medicine, rheumatology, general, plastic and reconstructive surgery, chirosurgery and neurology	Same	Same	Same	Same	Yes
Cooling Time	Approx. 8 hours at 43°F	Up to 9½ hours	Approx. 8 hours	Up to 10 hours	Approx. 6-8 hours	Yes
Cold Source	Water - Ice	Water - Ice	Water - Ice	Frozen Gel	Ice & Water	Yes
Operating Temperature Range	39°F to 59°F depending on ambient air temp	Unstated	32°F - 70°F depending on ambient air temp	Minimum temp. 38°F	Unstated	Yes
Power Supply	6 VDC from 115/230 VAC 50/60 Hz	12 VDC from 110 VAC 60Hz	12 VDC from 110 VAC 60Hz	12 VDC from 110 VAC 60Hz	Gravity flow only	Yes
Ground Leakage Current	<55 micro-amps	<55 micro-amps	<55 micro-amps	<55 micro-amps	<55 micro-amps	Yes
Recirculating Fluid	4:1 mixture of water and alcohol - 250 ml.	Water	Water -	Water	Water	Yes
Disposable cuff covers	Yes	Yes	Yes	Yes	Yes	Yes
Cuff	5 styles/sizes	1 multi-use universal	4 styles, 4 sizes	3 styles, 1 size ea.	4 styles, 2 sizes ea.	Yes
Performance Standards	UL-544	UL-544	UL-544	UL-544	Non-electric	Yes
Weight	Approx. 12.75 lb. filled	Approx. 8 to 12 lb. filled	Approx. 24 lb. w/ cooler	Approx. 8.9 lb. filled	Approx. 10 lb. filled	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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 (Premarket 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 premarket 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: K964354

Device Name: ARTROCOOL™ WATER CIRCULATING COLD PACK

Intended Use:

1. Localized cold therapy 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964354

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109) (Optional format 1-2-96)