

AUG 20 2003

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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

SPONSOR: Cryonic Medical North America
1350 Danielson Rd.
Montecito, CA 93108
805.886.8168

Contact: Sandra Williamson
610.470.7693

DEVICE NAME: CRYOTRON 2[®] Cryotherapy Device
COMMON OR USUAL NAME: Cryotherapy Device
DEVICE CLASSIFICATION: Class II
PREDICATE DEVICES: Gebauer's Instant Ice, K021726, Product Code MLY

DEVICE DESCRIPTION: The CRYOTRON 2[®] Cryotherapy Device delivers a topical spray of compressed medical-grade carbon dioxide. The patented technology of the CRYOTRON 2[®] Cryotherapy Device uses the natural expansion of liquid CO₂ to create a cold spray of micro-crystals delivered under pressure. Using a gradual sweeping motion, the user applies the spray to the treatment site for 30-60 seconds at a distance of 3-5 inches. Rapid cooling (thermal shock) occurs when the spray sublimates (passes directly from solid (ice) phase to gas phase) as it contacts the skin.

The CRYOTRON 2[®] Cryotherapy Device consists of four components that are housed in a mobile cart:

- A pistol-grip hand-piece that delivers the carbon dioxide spray.
- An electronic console/control panel that provides operational information to the user.
- A rechargeable battery.
- A cylinder of compressed medical-grade carbon dioxide gas (sold separately).

An infrared temperature measurement system continuously monitors the temperature of the skin surface. The skin surface temperature is displayed on the electronic console, and a red LED on the pistol-grip hand-piece flashes when the skin surface temperature falls to 4°C. An optional laser pointer within the pistol-grip hand-piece provides a visual indication of the zone where the skin temperature is measured.

The CRYOTRON 2[®] Cryotherapy Device is for use by, or on the order of a Physician, or by a trained, credentialed clinician.

INTENDED USE: The CRYOTRON 2[®] Cryotherapy Device is for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries, and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandra Williamson
Regulatory Consultant
Cryonic Medical North America
1350 Danielson Road
Montecito, California 93108

Re: K030281

Trade/Device Name: CRYOTRON 2® Cryotherapy Device
Regulatory Class: Unclassified
Product Code: MLY
Dated: May 22, 2003
Received: May 27, 2003

Dear Ms. Williamson:

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.

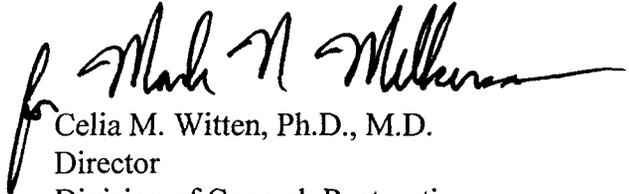
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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) 594-4659. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030281

Device Name: CRYOTRON 2® Cryotherapy Device

INDICATIONS/CONTRAINDICATIONS:

The CRYOTRON 2® Cryotherapy Device is for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries, and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030281

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____