

SECTION E

510(k) Summary May 7, 2002

Device Trade Name: Gebauer's Instant Ice™ (Mist Spray and Stream Spray)

Common Name: Cold Spray

DEC 1 2 2002

Establishment Registration Number: 1519179

Classification: I (Proposed)

Panel: General & Restorative Surgery

Device Product Code: 89MLY

Device Classification Name: Vapocollant (I believe this is a misspelling in the Classification Names Publication, FDA 95-4246 and should be Vapocoolant)

Special Controls: None

Manufacturer:

Gebauer Company
9410 St. Catherine Ave.
Cleveland, OH 44104

Contact

Amy J. Paukovits
Director of Regulatory Affairs and Quality Control
(216) 271-5252
(216) 271-5335 Fax

Predicate Devices:

The new device's name will be Gebauer's Instant Ice™ (Mist Spray and Stream Spray), to be sold as a non prescription over the counter product, which we claim is substantially equivalent to Gebauer's Ethyl Chloride® (Fine and Medium Nozzles) 510 (k) K991514 and Mueller® Coolant Cold Spray (21CFR 807.85 and Premarket Notification 510(k), "device in commercial distribution before May 28, 1976 are exempt from 510(k) submission), in distribution for over 40 years (as a non prescription cold spray) with no 510(k) number.

510(k) Application for Gebauer's Instant Ice™ (Stream and Mist Spray)

K021726

2052

Description

Gebauer's Instant Ice™ (Mist Spray and Stream Spray) is an over-the-counter device designed to deliver 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane) in a stream or mist spray. This mixture self-propels itself from the delivery system without the need for a propellant, because of the mixtures high vapor pressure.

This form of delivery is an appropriate mode of application when the consumer follows the labeled directions for use, cooling skin through rapid evaporation of non-,medicated volatile propellants

Intended Use of Device

Clinical conditions that may respond to the cooling effect's of Gebauer's Instant Ice™ Mist Spray are to use like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sports injuries. For Gebauer's Instant Ice™ Stream spray they are to use like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sports injuries and muscle spasms.

Technical Summary

As with both predicate devices, the cooling action experienced by the patient is caused by the evaporation of the chemical mixture from the patient's skin. The consumer applies pressure to the nozzle to dispense the aerosol product onto the skin. The material is contained in a can, filled under pressure, and dispensed using standard aerosol nozzle technology.

Determination Substantial Equivalence

There is demonstrated equivalency in basic product design and technology in indications for use, target population, and risk factors.

Temperature equivalency data shows that Gebauer's Instant Ice™ Stream is equivalent to Gebauer's Ethyl Chloride® Medium ($\pm 5.0^{\circ} \text{C}$) at the 95% confidence interval 80% of the time and that the temperature range of Gebauer's Instant Ice™ Mist Spray and Gebauer's Instant Ice™ Stream Spray are contained within the range of two currently marketed over-the-counter products. The 95% confidence intervals for average temperatures of Gebauer's Instant Ice™ Stream and Mist Spray products, Mueller® Coolant Cold Spray and Cramer® Cold Spray (Premarket Notification 510(k), "device in commercial distribution before May 28, 1976) were calculated, and the temperature interval between the Mueller® and Cramer® products was determined. Gebauer's Instant Ice™ Mist Spray and Gebauer's Instant Ice™ Stream Spray, while the same chemicals, have minor temperature characteristic differences, due to the physical properties of fluid dynamics and a slightly lower temperature in the mist,



DEC 12 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Amy J. Paukovits
Director, Regulatory Affairs
Gebauer Company
9410 St. Catherine Avenue
Cleveland, Ohio 44104

Re: K021726

Trade/Device Name: Gebauer's Instant Ice Mist and Stream Sprays
Regulation Name: Refrigerant, Topical (Vapocoolant)
Regulatory Class: Unclassified
Product Code: MLY
Dated: September 12, 2002
Received: September 13, 2002

Dear Ms. Paukovits:

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

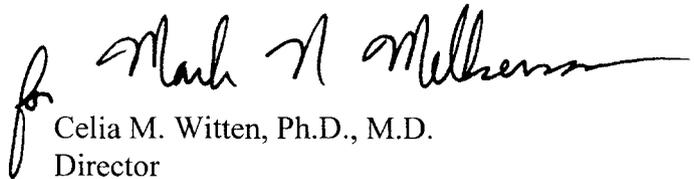
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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) 594-4659. 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,



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

510(k) Number (if known): K021726

Device Name: Gebauer's Instant Ice™ (Mist Spray and Stream Spray)

Indications For Use:

Gebauer's Instant Ice™ (Mist Spray): Use like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sports injuries.

Gebauer's Instant Ice™ (Stream Spray): Use like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sports injuries and muscle spasms.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

for Mark N. Melkera

Division of _____

Division of Ocular, Restorative
and Neurological Devices

510(k) Number K021726