

MAR 17 2004

SECTION E  
510(k) Summary August 29, 2003

K032671  
16P2

Device Trade Name: Gebauer's Skin Refrigerant (Mist Spray and Medium Spray)

Common Name: Cold Spray

Establishment Registration Number: 1519179

Classification: I (Proposed)

Panel: General & Restorative Surgery

Device Product Code: 89MLY

Device Classification Name: Vapocoolant

Special Controls: None

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

Contact: Amy Paukovits  
Director of Regulatory Affairs  
Tel: (216) 271-5252, ext. 20  
Fax: (216) 271-5335

**Predicate Device:**

Gebauer's Skin Refrigerant (Mist Spray and Medium Spray) 510(k) K031036

**Description:**

Gebauer's Skin Refrigerant (Mist and Medium Spray) Topical Anesthetic is a prescription device designed to deliver 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane) in a mist and medium spray. This mixture self-propels itself from the delivery system, which is designed to account for its low vapor pressure. The device delivery system is specifically designed to deliver a medium and mist spray of the Gebauer's Skin Refrigerant (Mist Spray and Stream Spray) mixture. The medium and mist spray is an appropriate mode of application when users follow directions for use, cooling the skin through rapid evaporation of the non-medicated volatile propellants. The new device, Gebauer's Skin Refrigerant, is identical in all aspects to Gebauer's Skin Refrigerant (Mist Spray and Medium Spray) 510(k) K031036, except that we are requesting expanded indications for use of the product on mucous membranes and breached and compromised skin. Both the new and predicate devices are indicated for use to control pain for pre-injection anesthesia, minor surgery, and minor sports injuries.

K032671  
26F2

The Medium Spray for the new device, like the predicate medium spray device, is also indicated for the management of myofascial pain caused by trigger points, restricted motion and muscle tension by using the Spray and Stretch® technique.

### **Intended Use of Device**

A vapocoolant (skin refrigerant) intended for topical application to skin, mucous membranes and minor open wounds. Gebauer's Skin Refrigerant controls pain associated with minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses, and sutures), injections (venipuncture, IV starts, cosmetic procedures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). The Medium Spray is also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

### **Technical Summary**

As with the predicate device, the cooling action experienced by the patient is caused by the evaporation of the chemical mixture from the patient's skin. The user 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 of Substantial Equivalence**

This premarket notification 510(k) "change being effected" is being submitted to expand the indications for use for Gebauer's Skin Refrigerant, Mist and Medium Stream. There is demonstrated equivalency in basic product design and technology, in indications for use, target population, and risk factors.

As stated above, the new device is identical in formulation, delivery system and packaging to the predicate device Gebauer's Skin Refrigerant, Mist and Medium Stream previously cleared for market under 510(k) K031036. The new device has expanded indications for use for topical application to the skin, mucous membranes and breached or compromised skin. Both the new and predicate devices are indicated for use to control pain associated with pre-injection anesthesia, minor surgery and minor sports injuries. The medium stream spray for both the predicate and new device have the identical indication for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension. The expansion of the indications for use is based on FDA's Blue Book #G95-1 and ISO-10993.



MAR 17 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K032671

Trade/Device Name: Gebauer's Skin Refrigerant (Mist Spray and Medium Stream Spray)  
Topical Anesthetic

Regulatory Class: Unclassified

Product Code: MLY

Dated: March 8, 2004

Received: March 10, 2004

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.

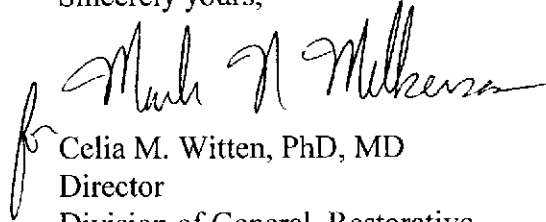
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set 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.

Page 2 - Ms. Amy Paukovits

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 "W".

Celia M. Witten, PhD, MD  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K032671

Device Name: Gebauer's Skin Refrigerant (Mist Spray and Medium Stream Spray) Topical Anesthetic

Indications for Use:

Gebauer's Skin Refrigerant (Mist Spray and Medium Spray) Topical Anesthetic: a vapocoolant (skin refrigerant) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passageways and the lips) and minor open wounds. Gebauer's Skin Refrigerant controls pain associated with minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses, and sutures), injections (venipuncture, IV starts, cosmetic procedures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). The Medium Spray is also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.


Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices** D-1

Page 1 of 1

510(k) Number K032671