K031036 1/2

JUL 10 2003

SECTION E

510(k) Summary June 20, 2003

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
(216) 271-5252, ext. 20
(216) 271-5335 Fax

Predicate Devices:

The new device's name is Gebauer's Skin Refrigerant (Mist Spray and Medium Spray), to be sold as a prescription product, which we claim is substantially equivalent to Gebauer's Ethyl Chloride® (Fine and Medium Nozzles) 510(k) K991514 and Gebauer's Instant ICE (Mist and Stream Spray) 510(k) K021726.

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 submitted in this application 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 is an appropriate mode of application when users follow the labeled directions for use, cooling 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 Instant ICE 510(k) K021726 except that we are requesting a prescription classification for the additional indications for use of pre-injection anesthesia, minor surgery and the management of myofascial pain by using the Spray and Stretch® technique. The new device, Gebauer's Skin Refrigerant has the identical indications for use as Gebauer's Ethyl Chloride 510(k) K991514.

Intended Use of Device
A vapocoolant (skin refrigerant) intended for topical application to control pain associated with minor surgical procedures (such as lancing boils, incisions and drainage of small abscesses), injections (venipuncture, IV starts) and the temporary relief of minor sports injuries. The Medium Spray is also intended for the treatment of restricted motion associated with myofascial pain caused by trigger points.

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 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
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 Gebauer's Instant ICE, 510(k) K021726. The temperature equivalency data previously submitted in 510(k) K021726, shows that Gebauer's Instant Ice ™ Stream is equivalent to Gebauer's Ethyl Chloride® Medium (± 5.0° C) at the 95% confidence interval 80% of the time. See data in 510(k) K021726, Section I Performance. The indications for use for the new device are identical to the predicate device, Gebauer's Ethyl chloride 510(k) K991514. Under the general indication for pre-injection anesthesia, we have added in parethesis some examples of the types of injections such as IV starts, and venipunture that may be performed with Gebauer's Skin Refrigerant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2003

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

Re: K031036
Trade/Device Name: Gebauer's Skin Refrigerant, Mist and Medium Sprays
Regulatory Class: Unclassified
Product Code: MLY, Refrigerant, Topical (Vapocoolant)
Dated: March 28, 2003
Received: April 21, 2003

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.

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,

Miriam C. Provost

for 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): K031036

Device Name: Gebauer's Skin Refrigerant (Mist Spray and Medium 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 control pain associated with minor surgical procedures (such as lancing boils, incisions and drainage of small abscesses), injections (venipuncture, IV starts) and the temporary relief of minor sports injuries. The Medium Spray is also intended for the treatment of restricted motion associated with myofascial pain caused by trigger points.

(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 _____

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K031036