

JUL 16 1999



GEBAUER COMPANY

Pharmaceutical Preparations

12991514

510(k) SUMMARY

Establishment Name: Gebauer Company
(Manufacturer)

Address: 9410 St. Catherine Ave.
Cleveland, OH 44104

Phone Number: (216) 271-5252

Fax Number: (216) 271-0910

Contact Person: Denise E. Spellman
(Official Correspondent)

Date Summary Prepared: 4/28/99

Device Names: Gebauer's Ethyl Chloride, Fine Nozzle
Gebauer's Ethyl Chloride, Medium Nozzle

Classification Name: Vapocollant

Predicate Products: Ethyl Chloride, USP Fine Nozzle
Ethyl Chloride, USP Medium Nozzle
Ethyl Chloride, USP 100 g Tube

Device Description:

Ethyl Chloride (Fine or Medium Nozzle) is a prescription device consisting of a single organic chemical (Ethyl Chloride) and a precise delivery system. The chemical is self-aerosolized to deliver a pinpoint stream spray.

Intended Use of Device:

Ethyl Chloride (Fine or Medium Nozzle): Ethyl Chloride is a vapocoolant (skin refrigerant) intended for topical application to control pain associated with injections, minor surgical procedures (such as lancing boils, incisions and drainage of small abscesses), and the temporary relief of minor sports injuries. It is also intended for the treatment of restricted motion associated with myofascial pain caused by trigger points.

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amended 7/14/99

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the new devices and predicate devices aerosolize Ethyl Chloride. The cooling action experienced by the patient is caused by the evaporation of Ethyl Chloride from the patient's skin. Both new and predicate devices contain Ethyl Chloride that meets the test specifications delineated in USP Ethyl Chloride raw material monograph. The only differences between the new devices and the predicate devices is the USP designation for the finished aerosolized product. The source and grade of the raw material is identical for the predicate and new devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Denise E. Spellman
QA/Regulatory Affairs Director
Gebauer Company
9410 St. Catherine Avenue
Cleveland, Ohio 44104

Re: K991514
Trade Name: Gebauer's Chloride Fine Nozzle
Regulatory Class: Unclassified
Product Code: MLY
Dated: June 3, 1999
Received: June 9, 1999

Dear Ms. Spellman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) 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 device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

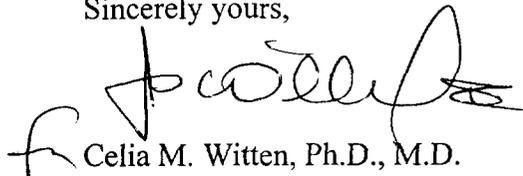
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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 device 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 device as described in your 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 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 device, 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

