May 7, 2019

Gebauer Company
Brittney Cooper
Sr. Regulatory Affairs and Quality Specialist
4444 East 153rd Street
Cleveland, Ohio 44128

Re: K190161
Trade/Device Name: Gebauer's Ethyl Chloride Topical Anesthetic Spray
Regulatory Class: Unclassified
Product Code: MLY
Dated: January 29, 2019
Received: January 30, 2019

Dear Brittney Cooper:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos Peña, PhD, MS
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190161

Device Name
Gebauer's Ethyl Chloride Topical Anesthetic Spray

Indications for Use *(Describe)*
Gebauer's Ethyl Chloride Topical Anesthetic Spray (Mist Spray, Fine Spray and Medium Spray): A vapocoolant (skin refrigerant) intended for topical application to control pain associated with injections (starting IV's and venipuncture), minor surgical procedures (such as lancing boils, or incision and drainage of small abscesses), and the temporary relief of minor sports injuries. The Fine and Medium Sprays are also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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GEBAUER COMPANY

510(k) Summary—K190161

This 510(k) Summary is being submitted in accordance of 21 CFR Part 807.92.

I. SUBMITTER

Owner:	Gebauer Company 4444 East 153rd Street Cleveland, OH 44128 (216) 581-3030
Contact Person:	Brittney Cooper Gebauer Company 4444 East 153rd Street Cleveland, OH 44128 (216) 581-3030
Date Prepared:	May 6, 2019

II. DEVICE

Trade Name:	Gebauer's Ethyl Chloride Topical Anesthetic Spray
Common Name:	Cold Spray
Classification Name:	Refrigerant Topical, Vapocoolant
Product Code:	MLY

III. PREDICATE DEVICE:

Primary:	Gebauer's Ethyl Chloride (Fine Spray and Medium Spray) K991514 Legally marketed medical device
Secondary:	Gebauer's Pain Ease Skin Refrigerant (Mist Spray and Medium Spray) Topical Anesthetic

IV. DESCRIPTION

Gebauer's Ethyl Chloride Topical Anesthetic Spray is a prescription device designed to deliver ethyl chloride in a mist, fine or medium spray. This chemical self-propels itself from the delivery system, which is designed to account for its low vapor pressure. The device is packaged in either a pharmaceutical glass bottle or steel aerosol can with several variations of nozzles. The patient contact is less than ten seconds and the skin is cooled through rapid evaporation of the non-medicated volatile propellant. The new device, Gebauer's Ethyl Chloride is identical in all aspects to the predicate device, Gebauer's Ethyl Chloride 510(k) K991514, with the exception of revised precautions and warnings and information regarding biocompatibility and USP <51> Antimicrobial Effectiveness Testing.

V. INDICATIONS FOR USE OF DEVICE

The Indications for Use is similar to the predicate devices.

Gebauer's Ethyl Chloride Topical Anesthetic Spray (Mist Spray, Fine Spray and Medium Spray): A vapocoolant (skin refrigerant) intended for topical application to control pain associated with injections (starting IV's and venipuncture), minor surgical procedures (such as lancing boils, or incision and drainage of small abscesses), and the temporary relief of minor sports injuries. The Fine and Medium Sprays are also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

VI. TECHNICAL SUMMARY

The new device has the same technical characteristics as the predicate device including materials, design, and energy source. There are no technological differences between the predicate and the new device. As with the predicate device, the cooling action experienced by the patient is caused by the evaporation of the chemical 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 steel aerosol can or pharmaceutical glass bottle, filled under pressure, and dispensed using standard aerosol nozzle technology. The only difference is product fill volume which is 3.9 fl. oz in the new device versus the predicate device which is 3.5 fl. oz. This change does not impact the performance of the device, only the number of uses per can or bottle. See table below for the comparison between the new device and the predicate:

	Comparison Chart – Technological Characteristics		
Trade Name	Gebauer's Ethyl Chloride *Predicate Device*	Gebauer's Pain Ease Skin Refrigerant (Mist Spray and Medium Spray) Topical Anesthetic *Predicate Device*	Gebauer's Ethyl Chloride Topical Anesthetic Spray *New Device*
Product Design	Pressurized dispensing container which includes the vapocoolant, steel aerosol can, or pharmaceutical glass bottle, valve (if a can) and actuator.	Pressureized dispensing container which includes the vapocoolant, aerosol can, valve and actuator.	Pressurized dispensing container which includes the vapocoolant, steel aerosol can, or pharmaceutical glass bottle, valve (if a can) and actuator.
Indication for Use and Intended Use	<u>Gebauer's Ethyl Chloride (Fine and Medium Nozzles):</u> Gebauer's Ethyl Chloride is 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 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.	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 Pain Ease Skin Refrigerant controls pain associated with minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses, and	*Gebauer's Ethyl Chloride Topical Anesthetic Spray (Mist Spray, Fine Spray and Medium Spray): A vapocoolant (skin refrigerant) intended for topical application to control pain associated with injections (starting IV's and venipuncture), minor surgical procedures (such as lancing boils, or incision and drainage of small abscesses), and the temporary relief of minor sports injuries. The Fine and Medium Sprays are also intended for the treatment of*

		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.	*myofascial pain caused by trigger points, restricted motion and muscle tension.*
Product Fill Volume	3.5 fl. oz. (103.5 mL)	3.5 flo. Oz. (103.5 mL)	3.9 fl. oz. (116 mL)
Vapocoolant Composition	Ethyl Chloride (100%)	1,1,1,3,3 Pentafluoropropane (HFC 245fa high purity) and 1,1,1,2 Tetrafluoroethane (HFC 134a pharmaceutical grade).	Ethyl Chloride (100%)
Energy Delivered	Thermal energy via Refrigerant Spray.	Thermal energy via Refrigerant Spray.	Thermal energy via Refrigerant Spray.
Vapocoolant Discharge Method	Depress the actuator to release the vapocoolant.	Depress the actuator to release the vapocoolant.	Depress the actuator to release the vapocoolant
Method of Application	Direct spray application to intact skin	Direct spray application to intact skin, intact oral mucous	Direct spray application to intact skin.

		membranes and minor open wounds.	
Environmental Compatibility	Flammable.	Non-Flammable.	Flammable.
Mechanical Safety	Mechanism has positive shut-off release.	Mechanism has positive shut-off release.	Mechanism has positive shut-off release.

VII. DETERMINATION OF SUBSTANTIAL EQUIVELANCE

This premarket notification 510(k) "change being effected" is being submitted to revise, remove or include specific information on the labeling identified and addressed within this pre-market submission. 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 Ethyl Chloride, 510(k) K991514.

Labeling
The new device has revised, removed or added information on the device labeling. The predicate device contained precautions and warnings not representative of clinical use of the device whereas the new device is labeled in accordance with the biocompatibility requirements of ISO 10993-1. Additionally, the labeling of the new device was revised to include information regarding USP <51> Antimicrobial Effectiveness Testing. Both the new and predicate devices are indicated for use to control pain associated with minor surgical procedures (such as lancing boils, incisions and drainage of small abscesses), injections and the temporary relief of minor sports injuries. The stream applications are also intended for use as a counterirritant in the management of myofascial pain, restricted motion and muscle tension. The new device labeling is substantially equivalent to the predicate device.

VIII. PERFORMANCE DATA

The predicate and new devices use the same materials, design and energy source and no technological differences exist. No changes were made to the device, use of the device, production of the device or output of the device. To support the labeling changes and to demonstrate that changes do not impact substantial equivalence, the following tests were performed:

Biocompatibility
Gebauer's Ethyl Chloride Topical Anesthetic Spray is categorized according to ISO 10993-1 as a surface device that has limited ($\leq$ 24 hours) contact with intact skin.

The relevant endpoints for the device are cytotoxicity, sensitization and irritation. Testing included in the submission support the biocompatibility of the device.

USP <51> Antimicrobial Effectiveness Testing (Preservative Effectiveness)
Testing was performed in accordance with USP <51> to demonstrate that the product acts as its own preservative and does not support growth of microorganisms during use. All test method acceptance criteria were met.

IX. CONCLUSION

Based on the information above and within this submission, it is concluded that the new Ethyl Chloride device is safe and effective for its intended use and is substantially equivalent to the predicate device.