October 27, 2017

Gebauer Company
Brittney Schmies
Regulatory Affairs Specialist
4444 East 153rd Street
Cleveland, Ohio 44128

Re: K172028
Trade/Device Name: Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist Spray and Medium Spray)
Regulatory Class: Unclassified
Product Code: MLY
Dated: September 25, 2017
Received: September 26, 2017

Dear Ms. Schmies:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172028

Device Name
Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist Spray and Medium Spray)

Indications for Use *(Describe)*
Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist Spray and Medium Spray): a vapocoolant (skin refrigerant) intended for topical application to skin, mucous membranes and minor open wounds. Gebauer's Pain Ease 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.

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.

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GEBAUER COMPANY

510(k) Summary — K172028

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 Schmies Gebauer Company 4444 East 153rd Street Cleveland, OH 44128 (216) 581-3030
Date Prepared:	October 27, 2017

II. DEVICE

Trade Name:	Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist Spray and Medium Spray)
Common Name:	Cold Spray
Classification Name:	Refrigerant Topical, Vapocoolant
Product Code:	MLY

III. PREDICATE DEVICE:

Primary:	Gebauer's Pain Ease (Mist Spray and Medium Spray) K032671 Legally marketed medical device

IV. DESCRIPTION

Gebauer's Pain Ease (Mist and Medium Spray) Topical Anesthetic Skin Refrigerant is a prescription device designed to deliver HFC 245fa high purity (1,1,1,3,3-Pentafluoropropane) and HFC 134a pharmaceutical grade (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 Pain Ease (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 Pain Ease, is identical in all aspects to the predicate device, Gebauer's Pain Ease (Mist Spray and Medium Spray) 510(k) K032671, except that the product can be applied to the skin for pre-injection anesthesia by cotton ball, cotton swab or gauze on intact skin. (If the skin is breached use this application method only with STERILE, disposable cotton balls, cotton swabs or gauze. The cotton balls, cotton swabs or gauze are not supplied with the device.) Both the new and predicate devices are indicated for use to control pain for pre-injection anesthesia, minor surgery, and minor sports injuries. 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.

V. INDICATIONS FOR USE

The indications for Use are the same as the predicate device.

Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist Spray and Medium Spray): a vapocoolant (skin refrigerant) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passage ways and the lips) and minor open wounds. Gebauer's Pain Ease 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.

VI. 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, or saturates a

cotton ball, cotton swab or gauze with the product and applies to the skin. The material is contained in a can, filled under pressure, and dispensed using standard aerosol nozzle technology. See table below for the comparison between the subject device and the predicate:

Comparison Chart – Technological Characteristics		
Trade Name	Gebauer's Pain Ease *Predicate*	Gebauer's Pain Ease *Subject Device*
Product Design	Pressurized dispensing container which includes the vapocoolant, aerosol can, valve and actuator.	Pressurized dispensing container which includes the vapocoolant, aerosol can, valve and actuator.
Intended Use	A vapocoolant (skin refrigerant) intended for topical application to skin, mucous membranes and minor open wounds. Gebauer's Pain Ease 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.	A vapocoolant (skin refrigerant) intended for topical application to skin, mucous membranes and minor open wounds. Gebauer's Pain Ease 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.
Product Fill Volume	3.5 oz. (103.5 mL)	3.5 oz. (103.5 mL)
Vapocoolant Composition	1,1,1,3,3 Pentafluoropropane (HFC 245fa high purity) and 1,1,1,2 Tetrafluoroethane	1,1,1,3,3 Pentafluoropropane (HFC 245fa high purity) and 1,1,1,2 Tetrafluoroethane

	(HFC 134a pharmaceutical grade).	(HFC 134a pharmaceutical grade).
Energy Delivered	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
Method of Application	Direct spray application to intact skin, intact oral mucous membranes and minor open wounds.	Direct spray application to intact skin, intact oral mucous membranes, and minor open wounds, or application via cotton ball, cotton swab or gauze on intact skin only. If the skin is breached this application method is to be used only with STERILE, disposable cotton balls, cotton swabs or gauze.
Environmental Compatibility	Non-Flammable.	Non-Flammable.
Mechanical Safety	Mechanism has positive shut-off release.	Mechanism has positive shut-off release.
Manufacturing Environment	Controlled Environment	Controlled Environment
Microbial Limits Testing	Tested in accordance with USP <61> and <62>.	Tested in accordance with USP <61> and <62>.
Biocompatibility Testing	In accordance with ISO 10993 for dermal irritation, sensitization, cytotoxicity, oral mucosal irritation, acute dermal toxicity.	In accordance with ISO 10993 for dermal irritation, sensitization, cytotoxicity, oral mucosal irritation, acute dermal toxicity.
Target Population	General	As the safety for use of the device in pediatric patients has not been established, it is recommended the device should not be used on patients under four without consultation of a pediatrician.
Boiling Point	44.6°F (7.0°C)	44.6°F (7.0°C)
Storage Temperature	Do not store at temperatures above 50°C (120°F)	Do not store at temperatures above 50°C (120°F)
Shelf Life	3 years	3 years

VII. DETERMINATION OF SUBSTANTIAL EQUIVELANCE

This premarket notification 510(k) is being submitted to expand the application methods in the instructions for use for Gebauer's Pain Ease, 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 Pain Ease, Mist and Medium Stream previously cleared for market under 510(k) K032671. The new device has expanded instructions for use to apply the product by either spraying directly on the skin or saturating a cotton ball, cotton swab or gauze on intact skin. (If the skin is breached use this application method only with STERILE, disposable cotton balls, cotton swabs or gauze. The cotton balls, cotton swabs or gauze are not supplied with the device.) Both the new and predicate devices are indicated for use to temporarily control pain associated with pre-injection anesthesia, minor surgery and minor sports injuries. The medium stream spray for both the predicate and new device has the identical indication for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

VIII. PERFORMANCE DATA

The predicate and subject devices use the same materials, design and energy source and no technological differences exist. Tests were selected and performed to ensure the subject device's performance, with the new method of application, is equivalent as the predicate. To demonstrate equivalence the following test was performed:

Side-by-Side Temperature & Output Bench Testing
Comparative testing was conducted to demonstrate equivalence between direct topical application via spraying and topical application using cotton ball, cotton swab or gauze. The testing was conducted to determine the temperature and output of the predicate and subject devices

Summary
Based on the temperature data generated, the subject device was found to have a safety and effectiveness profile that is similar to the predicate device.

IX. CONCLUSION

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