August 27, 2026

Gebauer Company
Amy Paukovits
Official Correspondent
4444 E. 153rd St.
Cleveland, Ohio 44128

Re: K260870
Trade/Device Name: Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist and Medium Spray)
Regulatory Class: Unclassified
Product Code: MLY
Dated: March 17, 2026
Received: March 17, 2026

Dear Amy 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHUN XU -S

For Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260870

Device Name

Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist 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, 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 temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions).

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

K260870 – 510(k) SUMMARY

Submitter Information

Company Name:	Gebauer Company
Company Address:	4444 East 153rd street Cleveland, OH 44128
Company Phone:	(216) 581-3030
Company Facsimile:	(216) 581-4970
Contact Person:	Amy Paukovits Director of Regulatory and Quality Affairs amy.paukovits@gebauer.com
Date:	8/26/2026

Device Identification

Device Trade Name:	Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist and Medium Spray)
Common Name:	Cold Spray (Skin Refrigerant)
Models:	0386-0008-13 – Medium Stream, 3.9 fl. oz. (115 ml) 0386-0008-12 – Mist Spray, 3.9 fl. Oz (115 ml) 0386-0008-14 – Medium Spray, 1.2 fl. Oz. (35 ml) 0386-0008-11 – Mist Spray, 1.2 fl. Oz. (35 ml)

Classification Name(s):	Vapocoolant Device
Regulation(s):	Unclassified
Device Class:	Unclassified
Product Code(s):	MLY
Advisory Panel:	Physical Medicine

Identification of Predicate Devices

The Subject Device is substantially equivalent to the following devices:

Device Name	Classification Name/ Regulation	Product Code	510(k) Number	Clearance Date
Gebauer's Pain Ease	Vapocoolant Device/Unclassified	MLY	K172028	10/27/2017
PainFreeze II	Vapocoolant Device/Unclassified	MLY	K232674	2/12/2024

Device Description

The Subject Device consists of a chemical blend of 90% HFO-1233zd (Trans-1 -chloro- 3,3,3-trifluoropropene) and 10% HFO-1234ze (trans- 1,3,3,3-tetrafluoroprop- 1 – ene). The blend self-propels itself from the aerosol delivery system which is designed to account for its low vapor pressure. The delivery systems consist of an aluminum aerosol can, valve and actuator. The blend produces a cooling effect upon contact with the skin, intact mucous membranes, and minor open wounds, when delivered in either a medium stream or mist spray. The blend begins to evaporate immediately upon contact with the skin, the evaporation rate of the blend is what produces the coldness.

Both the Subject Device and the Predicate Devices can be applied via direct spray or by following cotton application using a cotton ball, or gauze (if the skin is breached use this application method with only STERILE, disposable cotton balls or gauze. The cotton balls or gauze are not supplied with the device).

Indications for Use

Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist 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).

Summary of Technological Characteristics

Technological Comparison Table – Subject & Predicate Devices				
Comparison Feature	**Subject Device**	**Predicate Device: Gebauer's Pain Ease**	**Predicate Device: PainFreeze II**	**Similarities/Differences**
Device Name	Gebauer's Pain Ease	Gebauer's Pain Ease	PainFreeze II	
Manufacturer	Gebauer Company	Gebauer Company	Nuance Medical, Inc.	
510(k) Number	K260870	K172028	K232674	
Indications for Use	Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist and Medium Spray): a vapocooalant (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).	Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist 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 management of myofascial pain caused by trigger points, restricted motion and muscle tension.	PainFreeze II Medium Strem and Mist Spray are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passageways, and the lips) and minor open wounds. PainFreeze II's skin refrigerant controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (lancing boils, incisions, drainage of small abscesses, and sutures), and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions).	The indications for the subject device do not include the statement "The Medium Spray is also intended for the management of myofascial pain caused by trigger points, restricted motion and muscle tension." The difference in indications does not impact the safety and efficacy of the device.
Product Configurations	Mist Spray Medium Stream Spray	Mist Spray Medium Stream Spray	Mist Spray Medium Spray	Same
Chemical Composition	HFO-1233zd (Trans- 1 - chloro-3,3,3-trifluropropene) 90 % and HFO-1234ze (trans-1,3,3,3-tetrafluororprop-1 – ene) 10%	1,1,1,3,3 Pentafluoropropane (HFC-245fa high purity) and 1,1,1,2 Tetrafluoroethane (HFC-134a pharmaceutical grade)	HFO-1233zd (Trans- 1 - chloro-3,3,3-trifluropropene) 60% and HFO-1234ze (trans-1,3,3,3-tetrafluororprop-1 – ene) 40%	Temperature performance testing demonstrates that the subject device achieves temperatures of 30°C or below and a temperature decrease of 1°C from ambient temperature across application methods. Biocompatibility testing was conducted in

Technological Comparison Table – Subject & Predicate Devices				
Comparison Feature	**Subject Device**	**Predicate Device: Gebauer's Pain Ease**	**Predicate Device: PainFreeze II**	**Similarities/Differences**
				accordance with ISO 10993-1 similar to the predicate devices, thereby supporting the biocompatibility of the subject device. Therefore, the difference in chemical composition does not raise increased safety and/or efficacy concerns compared to the predicate devices.
Container Size	3.9 fl. Oz., 1.2 fl. Oz. (115ml, 35 ml)	103.5ml	35ml, 115ml	The volume differs, however there is no impact on safety or efficacy.
Target Population	Adults, and 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	General	Adults	Same as predicates.
Patient Contact	Skin, intact mucous membranes, and minor open wounds.	Intact skin, intact mucous membranes, and minor open wounds.	Skin	Same as the K172028 predicate
Energy Delivery	Thermal energy via refrigerant spray.	Thermal energy via refrigerant spray.	Thermal energy via refrigerant spray.	Same
Vapocoolant Discharge Method	Depress the actuator to release the vapocoolant.	Depress the actuator to release the vapocoolant.	Handheld spray containers. Button on actuator is pressed.	Same as the K172028 predicate
Maximum Delivered Volume	10 grams	Not publicly available	Not publicly available.	Temperature performance testing demonstrates that the subject device achieves temperatures of 30°C or below and a temperature decrease of 1°C from ambient temperature across application methods. Biocompatibility testing was conducted in accordance with ISO 10993-1 similar to the predicate devices, thereby supporting the

Technological Comparison Table – Subject & Predicate Devices					
Comparison Feature	**Subject Device**		**Predicate Device: Gebauer's Pain Ease**	**Predicate Device: PainFreeze II**	**Similarities/Differences**
					biocompatibility of the subject device. Therefore, the difference in the maximum delivered volume does not raise increased safety and/or efficacy concerns compared to the predicate devices.
Degree of Temperature Decrease between application methods	Direct Spray (Min-Max)	Medium: 18-31°C Mist: 3-33°C	Not publicly available.	Not publicly available.	Temperature bench testing of the subject device demonstrates that the subject device achieves temperatures of 30°C or below and a temperature decrease of more than 1°C from ambient temperature, similar to the predicate devices Therefore, differences in the degree of temperature decrease do not raise increased effectiveness concerns compared to the predicate devices.
	Cotton Ball (Min-Max)	Medium: 7-10°C Mist: 6-13°C			
	Gauze (Min-Max)	Medium: 6-9°C Mist: 7-13°C			
Boiling Point	14.0ºC		7.0ºC	-3.0 +/-3ºC	Bench temperature testing performed demonstrates the device performance is as effective as the predicate devices.
Mechanism of Action and Operating Principle	Cooling by application of refrigerant. Direct spray application to intact skin, intact oral mucous membranes, and minor open wounds, or application via cotton ball, or gauze.		Direct spray application to intact skin, intact oral mucous membranes, and minor open wounds, or application via cotton ball, cotton swab or gauze.	Cooling by application of refrigerant; Dispensing valve on canister is depressed to release the refrigerant	Same as the K172028 predicate device.
Flammability	Non-flammable		Non-flammable	Non-flammable	Same
Mechanical Safety	Mechanism has positive shut-off release.		Mechanism has positive shut-off release.	Mechanism has positive shut-off release	Same
Manufacturing Environment	Controlled Environment		Controlled Environment	Not publicly available.	Same

Technological Comparison Table – Subject & Predicate Devices				
Comparison Feature	**Subject Device**	**Predicate Device: Gebauer's Pain Ease**	**Predicate Device: PainFreeze II**	**Similarities/Differences**
Microbial Limits Testing	Tested in accordance with USP <61> and <62>.	Tested in accordance with USP <61> and <62>.	Not publicly available	Same
Biocompatibility Testing	Cytotoxicity Sensitization Irritation (Skin and Oral Mucosal) Acute Systemic Toxicity Material Mediated Pyrogenicity	In accordance with ISO 10993 for dermal irritation, sensitization, cytotoxicity, oral mucosal irritation, acute dermal toxicity	Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material Mediated Pyrogenicity	The Subject Device was tested for Material Mediated Pyrogenicity, similar to the K232674 predicate device
Shelf-Life	2 years	3 years	24 months	Shelf-life testing conducted for the subject device demonstrates there are no increased safety and/or effectiveness concerns compared to the predicate devices.
Storage Temperature	Do not store at temperatures above 50ºC	Do not store at temperatures above 50ºC	Not to exceed 49 ºC	Same as the K172028 predicate device.
Acidity	≤1ppm (w/w)	Not Publicly Available	Not publicly available	Acidity per USP <541> was established for the subject device to ensure safety when applied to skin.

Non-Clinical Testing

Assessments were performed that includes the following:

- Side-by-Side Temperature Comparison – comparative testing demonstrated similar temperatures to the predicate.
- Biocompatibility – Evaluations were conducted per ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process for devices in contact with intact mucous membranes, compromised skin and a limited exposure (<24 hours). Evaluations included:
    - Cytotoxicity
    - Sensitization
    - Skin Irritation
    - Oral Mucosal Irritation
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity

All test criteria were successfully met for each evaluation.

Shelf Life Testing

The following evaluations were conducted at defined intervals to support the two-year shelf life of the subject device, including:

- Visual Inspection
- Minimum Fill
- GC Purity
- GC Composition
- Non-Volatile Residue
- Appearance
- Microbial enumeration/Presence of microorganisms
- Acidity

Test criteria were met at each assessment interval, which demonstrated the Subject Device's stability

Clinical Testing

Not Applicable

Conclusions

Based on the information above, it is concluded that the Subject Device (Gebauer's Pain Ease Topical Anesthetic Skin Refrigerant (Mist and Medium Spray) is substantially equivalent to the K172028 and K232674 predicate devices.