December 21, 2020

623 Medical, LLC
% James Fentress
Director of Research and Development
Gilero, LLC
635 Davis Drive, Suite 100
Morrisville, North Carolina 27560

Re: K202782
Trade/Device Name: num Vapocoolant™
Regulatory Class: Unclassified
Product Code: MLY
Dated: September 16, 2020
Received: September 22, 2020

Dear James Fentress:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202782

Device Name
num Vapocoolant(TM)

Indications for Use *(Describe)*
nüm is a sterile topical anesthetic spray – 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

**Company Name:** Gilero, LLC
**Company Address:** 635 Davis Drive Suite 100
Morrisville, NC 27560
**Company Phone:** +1 (919) 595-8220

**Official Contact:** Jim Fentress
**Phone:** +1 (919) 595-8236
**E-mail:** jfentress@gilero.com

**Submission Date:** September 17, 2020

**Device Identification:**

| | |
|---|---|
| Trade Name: | num Vapocoolant™ |
| Common Name: | Cold Spray |
| Device Class: | Unclassified |
| Regulation Number: | N/A - unclassified |
| Regulation Name: | Refrigerant, Topical (Vapocoolant) |
| Product Code: | MLY |
| Review Panel: | Physical Medicine |

**Predicate Device:**

| | |
|---|---|
| Manufacturer: | Gebauer Company |
| Trade Name: | Gebauer's Skin Refrigerant, Mist and Medium Sprays |
| 510(k): | K031036 |

**Device Description:**
num Vapocoolant is a sterile-fluid-path, single-use, prescription device that delivers a vapocoolant mixture of 95% r254fa (1,1,1,3,3-Pentafluoropropane) and 5% 134a (1,1,1,2-Tetrafluoroethane). The vapocoolant is stored in a sealed canister within the Main Body of the device. When dispensed from the canister, this mixture self-propels itself from the delivery system using its vapor pressure as propellant. Propellant leaving the device exits through the Nozzle which is engineered to produce a mist spray. When the vapocoolant reaches the skin, cooling achieved through rapid evaporation of the non-medicated volatile products, and through the cooling capacity of the low-temperature evaporating vapocoolant. Device sterility is achieved through electron beam sterilization and maintained through protective Tyvek lidstock on the top of the nozzle, and a Cap in the base of the Main Body.

Nüm Vapocoolant is intended to be used by trained nurses, healthcare professionals, and pharmacists, in professional healthcare facilities.

**Indications for Use:**
nüm is a sterile topical anesthetic spray – 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.

**Technological Characteristics and Substantial Equivalence:**
The following chart presents an overview of comparisons between the subject device (num Vapocoolant), and the predicate device (Gebauer's Skin Refrigerant):

| Device Attribute | SUBJECT: [Gilero] num Vapocoolant™ | PREDICATE: [Gebauer] Skin Refrigerant | Assessment of Equivalence |
|---|---|---|---|
| **Device Class** | Unclassified | Unclassified | Equivalent |
| **Device Classification Name** | Refrigerant, Topical (Vapocoolant) | Refrigerant, Topical (Vapocoolant) | Equivalent |
| **Regulation Number** | N/A - unclassified | N/A - unclassified | Equivalent |
| **Product Code** | MLY | MLY | Equivalent |
| **Indications for Use and Intended Use** | nümis a sterile topical anesthetic spray – vapocoolant (skin refrigerant) intended for topical application to 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. | 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 | Equivalent<br><br>The indications for use and intended use of the subject device and predicate device are equivalent.<br><br>Since the num device only exists as a mist spray, additional indications for a medium spray (with its different spray pattern) do not apply.<br><br>Although the num device is provided sterile, this is descriptive and does not alter the indications or intended use. |
| **Intended Users** | Licensed healthcare practitioners | Licensed healthcare practitioners | Equivalent.<br><br>Both devices are sold by prescription only and intended to be used by medical practitioners. |
| **Principles of Operation** | 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. | 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. | Equivalent |
| **Vapocoolant Composition** | 95% 254fa (1,1,1,3,3-Pentafluoropropane) and 5% 134a (1,1,1,2- | 95% 254fa (1,1,1,3,3-Pentafluoropropane) and 5% 134a (1,1,1,2- | Equivalent |

| Device Attribute | SUBJECT: [Gilero] num Vapocoolant™ | PREDICATE: [Gebauer] Skin Refrigerant | Assessment of Equivalence |
|---|---|---|---|
| | Tetrafluoroethane) | Tetrafluoroethane) | |
| **Technology and Design** | The num device provides a vapocoolant mixture consisting of a 95% 245fa and 5% 134a. The mixture provides a positive pressure relative to the surrounding environment so the vapocoolant itself is also the propellant necessary to dispense the vapocoolant from the container. The num device is provided sterile single-dose container.<br><br>When the spray actuator is depressed by the end user, the vapocoolant mixture travels through the misting nozzle under its own pressure. The nozzle separates the mixture into a fine mist which is directed towards the area of the patient where an anesthetic effect is desired.<br><br>Upon reaching the skin, cooling occurs through the rapid evaporation of the non-medicated volatile mixture. This localized cooling creates an anesthetic effect. | The Gebauer Mist device provides a vapocoolant mixture consisting of a 95% 245fa and 5% 134a. The mixture provides a positive pressure relative to the surrounding environment so the vapocoolant itself is also the propellant necessary to dispense the vapocoolant from the container. The Gebauer Mist is provided non-sterile in a multidose container.<br><br>When the spray actuator is depressed by the end user, the vapocoolant mixture travels through the misting nozzle under its own pressure. The nozzle (in the case of the Mist Spray) separates the mixture into a fine mist which is directed towards the area of the patient where an anesthetic effect is desired.<br><br>Upon reaching the skin, cooling occurs through the rapid evaporation of the non-medicated volatile mixture. This localized cooling creates an anesthetic effect. | Equivalent.<br><br>The vapocoolant mixture which reaches the patient consists of an identical mixture of non-medicated volatiles.<br><br>The num device contains only a single dose compared to the Gebauer device, however, the num device still produces an equivalent cooling effect when both devices are used in accordance with their IFUs,<br><br>Sterilization of the num device does not alter the chemistry of the volatiles.<br><br>These differences in technology and design raise no new types of safety or effectiveness questions with the subject device when compared to the predicate device. |
| **Biocompatibility** | Acceptable biological risk established by demonstrating that the device meets ISO 10993. See Section 15 – Biocompatibility. | Acceptable biological risk established by demonstrating that the device meets ISO 10993 | Equivalent. |
| **Environmental Compatibility** | Non-Flammable | Non-Flammable | Equivalent |
| **Sterilization** | Sterile SAL $10^{-6}$ | Non-sterile | Although the num device is offered in a sterile configuration, the vapocoolant chemistry remains unaltered after sterilization. The vapocoolant composition reaching the patient is the same between the sterile num device and the non-sterile Gebauer device. |

**Substantial Equivalence Discussion:**
num Vapocoolant™ is substantially equivalent to the predicate: Gebauer's Skin Refrigerant. The subject device and the predicate device have similar indications for use and intended use. Both devices are single-use devices that contain the same mixture of 95% 254fa (1,1,1,3,3-Pentafluoropropane) and 5% 134a (1,1,1,2-Tetrafluoroethane) with the operation principles being equivalent.

Differences are limited to external packaging, which is for aesthetic and marketing purposes only, and sterilization, which has been shown not to affect material composition. Any difference in materials between the two products has been evaluated through ISO 10993 testing, which demonstrates material safety. The information provided in this submission supports the safety and effectiveness of the subject device for its intended use and demonstrates substantial equivalence with the predicate device.

**Discussion of Non-clinical Tests:**
The following non-clinical tests were conducted to demonstrate substantial equivalence to the predicate device.

**Biocompatibility:**
The num Vapocoolant, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization (type and duration), in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Specific testing included:

- Cytotoxicity
- Sensitization

**Sterilization Validation:**
Num Vapocoolant is sterilized using radiation in accordance with a validated sterilization cycle. The following standards were referenced during the sterilization validation process:

- ISO 11137-1:2006 - Sterilization of health care products – Radiation – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013 - Sterilization of Health Care Products-Radiation-Part 2: Establishing the sterilization dose
- ISO 11137-3:2017 - Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control

**Performance Testing:**
Num Vapocoolant is tested to ensure the safety, reliability, and efficacy of the product:

- Device sterility
- Sterile barrier efficacy

- Sterile barrier usability
- Actuation force
- Vapocoolant performance
- Spray Production and Duration

**Conclusion**

The information in this submission supports the safety and efficacy of the subject device for its intended use and demonstrates substantial equivalence with the predicate device. The num Vapocoolant™ differences in external materials, technology and operation from the predicate device do not raise new questions about safety and effectiveness.