April 14, 2020

Vapocoolshot, Inc.
% Neil Ross
Chief Scientific Officer, Quality Affairs
N2Pharma, LLC
1071 Nandina Dr
Weston, Florida 33327

Re: K193349
Trade/Device Name: Vapocoolshot Mist
Regulatory Class: Unclassified
Product Code: MLY
Dated: October 11, 2019
Received: December 3, 2019

Dear Neil Ross:

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,

For Vivek Pinto, PhD
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K193349

Device Name
Vapocoolshot Mist

Indications for Use *(Describe)*

The Vapocoolshot Mist is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Vapocoolshot Mist is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the 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.

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K193349 – 510(k) Summary

Vapocoolshot Inc. – Vapocoolshot Mist

I. SUBMITTER

Owner:
Vapocoolshot Inc.
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(561) 420-8330 (fax)

Contact Person:
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Jupiter FL, 33458
(561) 306-3434 (m)
(561) 427-0420 (o)

Date Prepared: February 28, 2020

1. Subject Device:

Trade/Device Name: Vapocoolshot Mist (Model VM11000)

Common Name: Refrigerant, Topical (Vapocoolant)

Review panel: Physical Medicine
Product code: MLY

2. Primary Predicate Device:

Gebauer's Pain Ease (Mist Spray & Stream Spray)
Gebauer Company.
K172028
Legally marketed medical device

3. Predicate 1:

Ouchless
Occam Design LLC
K093951

II. DEVICE DESCRIPTION

The Vapocoolshot Mist is a Vapocoolant (skin refrigerant) canister with an accessory nozzle that is intended for instant topical anesthetic. The Vapocoolshot Mist allows for the ease of use for a rapid, targeted, comfortable misting action of the refrigerant (cold like ice) onto the skin surface.

Vapocoolshot Mist is prescription device designed to deliver a standard mixture 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane) mist spray that will provide a transient refrigerant action. This mixture self-propels itself from the delivery system, which is designed to account for its low vapor pressure. The Vapocoolshot's nozzle, device's delivery system, controls the amount of the vapocoolant mixture that is dispensed. The mist spray configuration produces very fine droplets that create cooling at the points of contact. The Vapocoolshot produces a mist that contacts the skin surface at a targeted location. The skin is cooled through rapid evaporation of the non-medicated propellants.

Vapocoolshot Mist canister is equivalent to the Primary predicate device, Gebauer's Pain Ease. Both devices are indicated for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Vapocoolshot Mist is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).

Vapocoolshot Mist is equivalent to the Predicate 1, Ouchless. Both Vapocoolshot and Ouchless devices are indicated for topical application of refrigerant (cold like ice) to the skin and both devices have the same exact mixture blend of vapocoolant.

III. INDICATIONS FOR USE

The Vapocoolshot Mist is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Vapocoolshot Mist is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device Vapocoolshot Mist has similar technical characteristics as the Primary predicate device (Gebauer), including materials, design, and energy source. Refer to the following table for the comparison between the subject device Vapocoolshot Mist and the Primary predicate:

Comparison Chart – Technological Characteristics		
Trade Name	Vapocoolshot Mist K193349 *Subject Device*	Gebauer's Pain Ease K172028 *Primary Predicate*

Type	Rx	Rx
Product Design	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, cap and an accessory nozzle.	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap.
Indication for Use	The Vapocoolashot Mist is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Vapocoolshot Mist is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).	The vapocoolant (skin refrigerant) is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Vapocoolshot Mist can control pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).
Product Fill Volume	2oz (65 mL)	3.5oz (103.5mL)
Vapocoolant Composition	1,1,1,3,3-Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5%	1,1,1,3,3-Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC- 134a) 5%
Energy Delivered	Thermal Energy via Refrigerant Spray	Thermal Energy via Refrigerant Spray
Energy Deposited	N/A	N/A
Vapocoolant Discharge Method	Depress the Actuator Button to release the vapocoolant	Depress the Actuator Button to release the vapocoolant
Environmental Compatibility	Non-Flammable	Non-Flammable
Mechanical Safety	Mechanism has positive shut-off release.	Mechanism has positive shut-off release

The Vapocoolshot Mist device has similar technical and technological characteristics as the Predicate 1 (Ouchless), including materials, design, and energy source. Refer to the following table for the comparison between the Vapocoolshot Mist device and the Predicate 1:

Comparison Chart – Technological Characteristics		
Trade Name	Vapocoolshot K193349 *Subject Device*	Ouchless K093951 *Predicate 1*
Type	Rx	Rx
Product Design	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, cap and *accessory nozzle*.	Pressurized dispensing container, which includes the vapocoolant, canister, valve, and push button. (No canister cap, No actuator)
Indication for Use	The Vapocoolashot Mist is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Vapocoolshot Mist is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).	Used like ice for the temporary relief of minor pain.
Product Fill Volume	2oz (65 mL)	19mL
Vapocoolant Composition	1,1,1,3,3- Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5%	1,1,1,3,3- Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5%
Energy Delivered	Thermal Energy via Refrigerant Spray	Thermal Energy via Refrigerant Spray
Energy Deposited	N/A	N/A
Vapocoolant Discharge Method	Depress the Actuator Button to release the vapocoolant	Depress the Button to release the vapocoolant
Environmental Compatibility	Non-Flammable	Non-Flammable
Mechanical Safety	Mechanism has positive shut-off release.	Mechanism has positive shut- off release

Equivalence:

The Primary predicate (Gebauer) is legally marketed device. The subject device as a unit has similar intended use as the Primary predicate device.

The subject device is a prescription device as well as Primary predicate and Predicate 1.

The subject device has the same technological characteristics as the Predicate 1(Ouchless). There are no technological differences, including no changes in the materials, design, energy source, or other features of the device from those of the Predicate 1.

The subject, Primary predicate, and Predicate 1 devices use identical (substantially equivalent) chemical composition by type and percent of components: 245fa (1,1,1,3,3-Pentafluoropropane) at 95% of the total and 134a (1,1,1,2-Tetrafluoroethane) at 5% of the total mixture.

Labeling:

The labeling of subject device has been prepared to ensure the medical professional has adequate and clear instructions for safety and usage. The canister labeling, directions for use, safety and warning statements relating to the Vapocoolant Mist are equivalent to the Primary predicate (Gebauer) and Predicate 1(Ouchless).

V. PERFORMANCE DATA.

Biocompatibility

The subject device has Indirect Contact. The gas blend is approved for this clinical use, application and methodology. The materials are compatible.

Chemical Composition Confirmation

The subject device, Primary predicate and Predicate 1 are composed of identical aerosols profiles, which is 245fa (1,1,1,3,3-Pentafluoropropane) at 95% of the total and 134a (1,1,1,2-Tetrafluoroethane) at 5% of the total mixture.

The subject device's aerosol is checked and verified upon receipt from the aerosol supplier to ensure the same chemical profile as the Primary predicate (Gebauer).

Structural and Parts Composition

Engineering verification measurements were taken, and visual inspections were made to determine the Vapocoolashot Mist canisters, valves, and caps were equivalent to the Primary predicate (Gebauer).

Engineering verification measurements were taken, and visual inspections were made to determine the Vapocoolshot was equivalent to the Predicate 1(Ouchless).

Directions for Use (Clinical Use) Application and Methodology:

All key elements of the Directions for Use (DFU) between the Primary predicate (Gebauer), Predicate 1 and the subject device are similar, including intended use, precaution statements, warning statements, and contraindication statements, and treatment regimen. No significant differences exist between the Predicate 1 (Ouchless) and subject device's Directions for

Use.

Side-by-Side Temperature & Output Bench Testing

Tests were selected and performed to ensure the subject device's output performances are similar as a whole with its Primary Predicate (Gebauer).

Comparative performance testing was conducted as it related to temperature output at the application surface and volume dispensed per actuation/total and equivalent results were demonstrated.

Stability Protocol and Shelf Life Testing

A stability protocol was developed to ensure that the identity, strength, quality, and purity of the product are maintained throughout its labeled dating period. Testing assessments were conducted under controlled conditions at room temperature and under accelerated conditions. All requirements were confirmed to meet established acceptance criteria.

Summary

Based on the performance evaluations conducted, Vapocoolshot Mist was found to be safe and effective to the Primary predicate (Gebauer).

VI. CONCLUSION

Based on the information provided in the submission, it is concluded that the Vapocoolshot Mist is safe and effective for its intended use and has demonstrated similar to the Primary predicated (Gebauer). The Vapocoolshot as a unit does not raise additional questions of safety, efficacy and effectiveness different from the Predicate 1 (Ouchless).