August 12, 2020

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

Re: K201248
Trade/Device Name: Syringe Holder accessory (VM03000)
Regulatory Class: Unclassified
Product Code: MLY
Dated: May 11, 2020
Received: May 14, 2020

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,

Amber Ballard, PhD
Assistant Director (Acting)
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)*

K201248

Device Name
Syringe Holder accessory (VM03000)

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)

The Syringe Holder accessory is intended to be attached to the Nozzle of the Vapocoolshot Mist and allows for the attachment of a user supplied syringe 1cc (4.5mm) to 3 cc (10.8mm) in diameter to facilitate the injection procedure following Vapocoolshot Mist application.

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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510(k) Summary

Vapocoolshot Inc. – Syringe Holder accessory

Type of 510(k) submission:	Traditional

1. Submitter:

510(k) submitter/ Owner:	Vapocoolshot, Inc. 1155 Main St, Suite 105 Jupiter, Fl. 33458 561-427-0420 (main) 561-420-8330 (fax)
Contact person:	Neil Ross Chief scientist neildonaldross@gmail.com
Date Prepared:	June 12, 2020

2. Subject device:

Name/Classification	Syringe Holder accessory for K193349
Special Controls:	None
Device Class:	unclassified
Review panel:	Physical Medicine
Product code:	MLY

3. Trade Name of Subject Device: Syringe Holder Accessory (VM03000)

4. Primary Predicate: Vapocoolshot Mist (Model VM11000)
Vapocoolshot, Inc.
K193349

Common Name	Cold Spray – 245fa (1,1,1,3,3-Pentafluropropane) and 134a (1,1,1,2-Tetrafluroethane)
Device:	Refrigerant, Topical (Vapocoolant)
Device Class:	Unclassified
Review panel:	Physical Medicine
Product code:	MLY

Predicate 1: Ouchless
Occam Design LLC
K093951

Basis for Submission: New accessory Device

I. DEVICE DESCRIPTION

The Syringe Holder accessory (K201248) on the Nozzle of the Primary predicate Vapocoolshot Mist (K193349), allows the attachment of a user supplied syringe diameter 1cc (4.5mm) to 3 cc (10.8mm) for the practitioner to focus on the transient blanching effect for the best rapid, targeted, comfortable and efficient use of the gas Blend misting action onto the skin surface accordance with the best judgment of the physician under aseptic conditions. The Primary predicate Vapocoolshot Mist (K193349) is a vapocoolant (skin refrigerant) canister with standard gas Blend 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane) that is designed to spray onto the skin surface for a comfort injection procedure. The vapocoolant cools the skin through rapid evaporation of the non-medicated propellants.

The subject device, Syringe Holder accessory (K201248) helps direct the site with the following efficient use of the gas Blend with the syringe: configures refrigerant gas to a mist, targets the transient blanche site, one handed use, keeps the syringe in the same path, and controls the amount of the vapocoolant mixture that is dispensed for the practitioner. Thus, the accessory device avoids over spraying and having to switch from a canister spray effect to a syringe injection technique that may have dissipated the transient numbing effect for comfort results.

The Syringe Holder accessory (K201248) is equivalent to the predicate 1 device, Ouchless. Both devices help direct for topical application of refrigerant (cold like ice) to the skin with the attachment of a user supplied syringe. Primary predicate Vapocoolshot Mist (K193349) is used for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The Primary predicate Vapocoolshot Mist (K193349) 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). Ouchless and Syringe Holder devices attach to a user supplied syringe with the same exact blend of vapocoolant. The Syringe Holder accessory is the attachment of the "introducer" of the user supplied syringe to the vapocoolant.

II. 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)

The Syringe Holder accessory is intended to be attached to the Nozzle of the Vapocoolshot Mist and allows for the attachment of a user supplied syringe 1cc (4.5mm) to 3 cc (10.8mm) in diameter to facilitate the injection procedure following Vapocoolshot Mist application.

III. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device Syringe Holder accessory (K201248) has similar technical characteristics as the Predicate 1 device (Ouchless). Refer to the following table for the comparison between the subject device Syringe Holder accessory, Primary Predicate Vapocoolshot Mist, and the Predicate 1, Ouchless:

The basic principle of attaching a canister to a user supplied syringe is similar with the Predicate 1 Ouchless and the Syringe Holder accessory as a unit.

Comparison Chart – Technological Characteristics			
Trade Name	Syringe Holder accessory *Subject Device* K201248	Vapocoolshot Mist K193349 *Primary Predicate*	Ouchless K093951 *Predicate 1*
Type	Rx	Rx	Rx
Product Design as a unit	Syringe Holder accessory.	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, cap and an accessory nozzle.	Pressurized dispensing container, which includes the vapocoolant, canister, valve, syringe attachment, and nozzle. (No canister cap, No actuator)
Indication for Use	The Syringe Holder accessory on the Nozzle of the Vapocoolshot Mist allows the attachment of a user supplied syringe diameter 1cc (4.5mm) to 3 cc (10.8mm) for the practitioner to focus on the transient blanching effect for best comfort and efficient results in accordance with the best judgment of the physician under aseptic conditions.	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) The Syringe Holder accessory is intended to be attached to the Nozzle of the Vapocoolshot Mist and allows for the attachment of a user supplied syringe 1cc (4.5mm) to 3 cc (10.8mm) in diameter to facilitate the injection procedure following Vapocoolshot Mist application.	Used like ice for the temporary relief of minor pain.
Attaches a syringe	Yes	No	Yes
Gas Blend type	N/A	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	N/A	N/A	N/A
Same Technology	Yes	Yes	Yes

Syringe controlled by Practitioner	Yes	Yes	Yes
Drug controlled by Practitioner	Yes	Yes	Yes
Syringe Attachment	Attaches to the syringe by one device	N/A	Attaches to the specific syringe based on 3 colors.

Equivalence:

The subject device as a unit has similar intended use as the Predicate 1, Ouchless.

The accessory "introducer" in the subject device, Syringe Holder Accessory attachment helps direct the user supplied syringe onto the refrigerant target blanche site similar to the predicate 1, Ouchless.

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

The subject device combined with the Primary predicate has the same technological characteristics as the Predicate 1, Ouchless. There are no technological differences of the device as a unit from those of the Predicate 1, Ouchless. The similarities between the subject device and Predicate 1 (Ouchless), are the ability to attach a user supplied syringe to the canister through an accessory attachment on the nozzle.

Labeling:

The labeling of subject device has been prepared to ensure the medical professional has adequate and clear instructions for safety and usage. The Syringe Holder accessory (K201248) attachment to the Nozzle of the Primary predicate, Vapocoolshot Mist (K193349) are equivalent to the Predicate 1 (Ouchless).

IV. PERFORMANCE DATA

Usability study was performed with the attachment of a user supplied syringe to the Nozzle with the Syringe Holder accessory (K201248) .

Biocompatibility:

The subject accessory device, Syringe Holder, has no contact with the gas Blend or the patient. The materials are biocompatible.

Chemical Composition Confirmation:

The subject device's material is checked and verified upon receipt from the supplier to ensure the same chemical profile.

Structural and Parts Composition:

Engineering verification measurements were taken, and visual inspections were made to determine the Syringe Holder accessory (K201248) when used with the Primary predicate were 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 Predicate 1 (Ouchless) and the subject device accessory attached to Primary predicate as a unit are similar. No significant differences exist

between the Predicate 1 (Ouchless) and subject device's Directions for Use as a unit.

Bench Testing:

Tests were selected and performed to ensure the subject device's performance, when attached to Vapocoolshot Mist (K193349), results are similar. Comparative performance testing was conducted as it related to attachment of a user supplied syringe as an accessory device. Usability testing performed on subject device as a unit for efficacy and safety as an accessory introducer.

Summary:

Based on the performance evaluations conducted, Syringe Holder Accessory (K201248) when used with the Primary Predicate Vapocoolshot Mist (K193349) were found to be safe and effective to the Predicate 1 (Ouchless).

V. CONCLUSION

Based on the information provided in the submission, it is concluded that the Syringe Holder accessory (K201248) is safe and effective for its intended use. The Syringe Holder accessory (K201248) attached to the Predicate Vapocoolshot Mist (K193349) as a unit does not raise additional questions of safety, efficacy and effectiveness different from the Predicate (Ouchless).