May 30, 2025

Vapocoolshot, Inc
Michal Lyzwa
Director of Product Development
950 Peninsula Corporate Circle
Suite 2011
Boca Raton, Florida 33487

Re: K243654
Trade/Device Name: DentalJect
Regulatory Class: Unclassified
Product Code: MLY
Dated: May 1, 2025
Received: May 2, 2025

Dear Michal Lyzwa:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.*

Submission Number *(if known)*

K243654

Device Name

DentalJect

Indications for Use *(Describe)*

The DentalJect™ is intended for topical application to intact mucous membrane (oral cavity). The DentalJect™ is used to target a minimally sized cooling area for lessening pain associated with injections.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) – Summary
# K243654
## Vapocoolshot, Inc
## DentalJect™
May 28, 2025

## Submitter Information


| | |
|---|---|
| Company Name: | Vapocoolshot, Inc |
| Company Address: | 950 Peninsula Corporate Circle<br>Suite 2011<br>Boca Raton, FL 33487 |
| Company Phone: | 1-833-266-5528 |
| Applicant: | Jacob Leibovici<br>Founder, Dentist<br>jleibovici@vapocoolshot.com |


## Subject Device Name and Classification

Trade/ Device Name: DentalJect™.
Review Panel: Physical Medicine
Product code: MLY

Regulation Number: Unclassified

Classification Name: Vapocoolant Device

Device Class: Unclassified

## Predicate and Reference Device Information

**Primary Predicate: K011666**

Trade/ Device Name : Chillit
Regulation Number : 872.1720
Classification Product code: EAT
Subsequent Product Code: MLY, DYZ, EKZ
Regulation Medical Specialty: Dental
510K Review Panel: Dental
Device Class: Class 2
Propellant: 1,1,1,2-Tetrafluoroethane (HFC-134a)
Intended use: Topical Anesthetic and Pulp Testing.

## Reference Device 1: K201248

Vapocoolshot Mist (Cooljet) 1-3cc Syringe Holder Accessory (K201248). Model # VM01050-00, Syringe Holder Accessory exclusively for K193349:
Device Classification Name: Vapocoolant device.
Classification Product Code: MLY
510K Review Panel: Physical Medicine
Legally Marketed medical device as a Syringe Holder 1-3cc accessory (K201248) to Cooljet Topical Anesthetic Canister (K193349).
Note: This Syringe Holder 1-3cc attachment (K201248) is an Accessory similar to the DentalJect™ Dental Connector for a dental syringe.

## Reference Device 2: K232674

Device Trade Name: PainFreeze II
Common Name: Cold Spray (skin refrigerant)
Classification Name: Vapocoolant Device
Regulation: Unclassified
Product Code: MLY
Device Class: Unclassified
Advisory Panel: Physical Medicine
Note: It is cleared for intact mucous membrane and the propellant blend contains HFO-1234 Ze 40% (Trans-1-3-3-3-Tetrafluoroprop-1-ene) that went through Biocompatibility testing 10993-1.
Legally Marketed medical device to replace PainFreeze I (K162218).

## DentalJect™ Device Description:

The DentalJect™ is a prescription device which attaches to a standard dental syringe and dispenses a non-medicated, non-flammable vapocoolant blend as a topical anesthetic for intact oral mucosa.

## Indication for Use:

The DentalJect™ is intended for topical application to intact mucous membrane (oral cavity). The DentalJect™ is used to target a minimally sized cooling area for lessening pain associated with injections.

## Equivalence to Marketed Device.

| Comparison Chart A<br>DentalJect™ with Primary Predicate Chillit | | |
|---|---|---|
| **Trade Name** | DentalJect™<br>***Subject Device*** | Chillit K011666<br>***Primary Predicate*** |
| **Type** | Rx | Rx |
| **Product Design** | Pressurized dispensing container, which includes the vapocoolant, canister and valve; Syringe barrel attachment Dental Connector; and DentalJect™ accessory nozzle (actuator).<br>(User Provided: needle and anesthetic carpule or dental syringe) | Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap. Accessory applicator.<br>(User Provided: needle, anesthetic carpule and dental syringe) |
| **Indication for Use** | The DentalJect™ is intended for topical application to intact mucous membrane (oral cavity). The DentalJect™ is used to target a minimally sized cooling area for lessening pain associated with injections. | Device indications for use:<br>1. Cooling Heat Sensitive Orthodontic wires<br>2. Topical anesthetic<br>3. Pulp Test the vitality of teeth. |
| **Product Fill Volume** | 40 grams<br>Aerosol Canister | Unknown (2001)<br>Aerosol canister |
| **Vapocoolant Composition** | HFO 1234 Ze: (trans- 1,3,3,3-tetrafluoroprop-1-ene) ±95.00% and Non-denatured Ethanol ±4.99% and Natural Spearmint Flavoring ±0.01% | 1,1,1,2-Tetrafluoroethane (HFC-134a)<br>Same for Inhaler |
| **Energy Delivery** | Thermal energy via refrigerant spray | Thermal energy via refrigerant spray |
| **Vapocoolant Discharge Method** | Depress the trigger to release the vapocoolant. | Depress the Actuator Button to release the vapocoolant. |
| **Environmental Compatibility** | Non-Flammable<br>Low GWP | Non-Flammable |
| **Mechanical Safety** | Mechanism has positive shut-off release. | Mechanism has positive shut-off release. |
| **Anatomical site application** | Intact Oral cavity mucous membrane | Mucous membrane and pulp testing tooth. |
| **Application method with associated kit components.** | Handheld spray canister with attached user provided dental syringe *used to target and minimize cooling area for lessening pain* in order to capture the fleeting topical anesthetic blanch effect from the refrigerant mist spray. | Handheld spray canister with an applicator to deliver the refrigerant mist spray for lessening pain similar to Gebauer method of spraying directly on a cotton ball or spraying into a cup and dipping the cotton ball in the liquid, then applying the cotton ball to the tissue. |

| Comparison Chart B<br>DentalJect™ with Reference Device 1 and 2 | | | |
|---|---|---|---|
| **Trade Name** | DentalJect™<br>**Subject device** | Syringe Holder 1-3cc accessory<br>K201248<br>**Reference Device 1** | PainFreeze II<br>K232674<br>**Reference Device 2** |
| **Type** | Rx | Rx | Rx |
| **Product Design as a unit** | Pressurized dispensing container, which includes the vapocoolant, canister and valve; Syringe barrel (11 to 13mm) attachment Dental Connector; and DentalJect™ accessory nozzle (actuator).<br>(User Provided: needle and anesthetic carpule or dental syringe) | Syringe Holder 1-3cc accessory.<br><br>Syringe Holder Accessory exclusively for K193349 Pressurized dispensing container.<br><br>(User Provided: needle, drug and medical syringe 1-3cc) | Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap.<br><br>(User Provided: needle, drug and medical syringe 1-3cc) |
| **Indication for Use** | The DentalJect™ is intended for topical application to intact mucous membrane (oral cavity). The DentalJect™ is used to target a minimally sized cooling area for lessening pain associated with injections. | The Vapocoolshot Mist(CoolJect) is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The CoolJect is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures) and minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries<br>(sprains, bruising, cuts, and abrasions).<br><br>The Syringe Holder accessory on the Nozzle of the Vapocoolshot Mist allows the attachment of a user supplied syringe diameter 1cc (4.5mm) to 3cc (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. | PainFreeze II Medium Stream and Mist Spray are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. PainFreeze II's skin refrigerant controls 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) |

| | | | |
|---|---|---|---|
| **Gas Blend type** | HFO 1234 Ze: (trans-1,3,3,3-tetrafluoroprop-1-ene) ±95.00% and Non-denatured Ethanol ±4.99% and Natural Spearmint Flavoring ±0.01% | N/A as Syringe Holder accessory attached exclusively to the CoolJect aerosol canister (K193349) Blend 1,1,1,3,3-Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5% with an accessory 1-3cc Syringe Holder (K201248) | HFO-1233 Zd 60% (Trans-1-Chloro-3-3-3-Trifluoropropene) / HFO-1234 Ze 40% (Trans-1-3-3-3-Tetrafluoroprop-1-ene).<br><br>Gen2 Low GWP Environmentally friendly transition |
| **Energy Delivery** | Thermal energy via refrigerant spray | N/A | Thermal energy via refrigerant spray |
| **Aerosol canister delivery propellant and vapocoolant** | Yes | Yes<br>(as attachment to the canister) | Yes |
| **Application Time to mist** | Canister's IFU 1-2 sec on<br>Intact oral mucosa | When Syringe Holder accessory attached:<br>Canister's IFU 4-10sec. | canister's IFU 4-10sec |
| **Method of application by spray to target a minimally sized cooling area** | Same | Same | Different.<br>Handheld spray canister with no applicator or accessory |
| **Syringe Attachment Accessory** | Yes<br>The DentalJect™ Syringe Connector is compatible with user provided dental syringes with barrel lengths in standard ranges of 60 to 80 mm and diameters ranging from 11mm to 13 mm. Examples of compatible syringes include type Clark-Waite(CW) and type Astra(A). | Yes<br>1-3cc Syringe Holder attaches as an Accessory to K193349 | N/A |

## Performance Data

### Clinical Testing

Not Applicable

### Non-Clinical Testing

#### Bench (Specification) Testing:

Tests were selected and performed to ensure the subject device, DentalJect™, met predefined requirements pertaining to fit, form and safe function. Bench testing included needle clearance testing verifying non-contact of spray on the user-provided dental needle; fit and form testing ensuring the adequate compatibility with user-provided dental syringes and flammability testing per CFR Part 16 §1500.45 to validate the non-flammable characteristics of the subject device vapocoolant blend.

#### Usability Testing:

End-User validation testing based on the FDA Guidance on Applying Human Factors and Usability Engineering was conducted across multiple intended user groups and under simulated use conditions.

#### Biocompatibility 10993-1:

The Biological Compatibility of the DentalJect™ was assessed per ISO 10993-1.

All of the results successfully met the test criteria for each of the following evaluations:

1. Cytotoxicity
   According to: ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

2. Sensitization
   According to: ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization

3. Irritation
   According to: ISO 10993-23:2021(E) - Biological evaluation of medical devices Part 23: Tests for irritation

4. Acute Systemic Toxicity
   According to: ISO 10993-11:2017(E) - Biological evaluation of medical devices –Part 11: Tests for systemic toxicity

5. Material Mediated Pyrogenicity
   According to: USP-NF – <151> Pyrogen Test (2017)

**Temperature Profile:**

Tests were selected and performed to ensure the subject device, DentalJect™, provided similar thermal profile characteristics on oral mucosa as the reference device Vapocoolshot Mist /CoolJect (Reference Device1) marketed device (K201248/K193349) provides on skin, per its intended use and directions for use.

**Stability:**

Shelf life and stability testing conducted as of the date of this report supports an initial shelf life of twenty-four (24) months, with testing ongoing to facilitate a three (3) year shelf life.

## Conclusion

The result of the evaluation demonstrates that the DentalJect™ is substantially equivalent to the identified predicate and references devices. Any differences between the Predicate and Reference devices have been mitigated through non-clinical bench testing.