February 12, 2024

Nuance Medical, LLC
Neal Hartman
Regulatory Affairs/Quality Assurance
5931 Sea Lion Place, Suite 113
Carlsbad, California 92010

Re: K232674
Trade/Device Name: PainFreeze II
Regulatory Class: Unclassified
Product Code: MLY
Dated: August 31, 2023
Received: September 1, 2023

Dear Neal Hartman:

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.

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232674

Device Name
PainFreeze II

Indications for Use *(Describe)*
PainFreeze II Medium Stream 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 (lancing boils, incisions, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K232674 - 510(K) SUMMARY

Submitter Information

Company Name:	Nuance Medical, Inc.
Company Address:	5931 Sea Lion Place, Suite 113 Carlsbad, CA 92010
Company Phone:	(760) 585-9548
Company Facsimile:	(760) 235-4572
Contact Person:	Neal Hartman Regulatory Affairs/Quality Assurance nealenhartman@gmail.com
Date:	January 29, 2024

Device Identification

Device Trade Name:	PainFreeze II
Common Name:	Cold Spray (Skin Refrigerant)
Models:	#1830 – Mist Stray, 115ml #1831 – Medium Stream, 115ml #1832 - -Mist Spray, 35ml #1833 - Medium Stream, 35ml
Classification Name(s):	Vapocoolant Device
Regulation(s):	Unclassified
Device Class:	Unclassified
Product Code(s):	MLY
Advisory Panel:	Physical Medicine

Identification of Predicate Devices

The System Device is substantially equivalent to the following device:

Device Name	Classification Name/Regulation	Product Code	510(K) Number	Clearance Date
Pain Freeze	Vapocoolant Device/ Unclassified	MLY	K162218	11/22/2016

Common Name: Cold Spray – 245fa (1.1.1.3.3-Pentafluorpropane) and 134a (1.1.1.2-Tetrafluoroethane)

Device Description

The Subject Device consists of a chemical blend of 60% HFO-1233zd (Trans-1-chloro-3,3,3- trifluoropropene) and 40% HFO-1234ze (trans- 1,3,3,3-tetrafluoroprop-1- ene) that produces a cooling effect upon contact with the skin, intact mucous membranes, and minor open wounds. The product is delivered in the form of an aerosol in either a mist or stream spray. The device's delivery system controls the amount of chemical blend that is dispensed, the mist spray configuration produces very fine droplets that cools at the points of contact. The stream spray configuration produces a pinpoint stream that contacts the skin surface at a specific single location. Upon contact with the skin, the product begins to evaporate immediately as it contacts the skin. The low evaporation rate of the product's chemical blend is what creates the coldness. The Subject Device is non- flammable and has a lower global warming potential than the predicate and provides equivalent performance.

The Subject Device is topically sprayed onto the skin. It creates a cooling effect on the surface of the application site by the immediate evaporation of the product from the skin surface.

With both product configurations, the evaporation creates the cold sensation. As the distance from the target surface is increased, the dispersion of the droplets in both the mist and stream is increased. Increasing the surface area of contact and decreasing the size of the droplets increases the evaporation rate. The increase in evaporation rate correlates to an increase in the cooling effect.

The chemical blend is incorporated in pressurized canisters, which will be offered in two (2) volumes 35 and 115 ml. The canister consists of a high-pressure canister, valve, and actuator.

Indications for Use

PainFreeze II Medium Stream 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 (lancing boils, incisions, drainage of small abscesses, and sutures), and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions).

Summary of Technological Characteristics

Table 10.1: Comparison Table – Subject & Predicate Devices

Comparison Feature	Subject Device	Predicate Device	Similarities/ Differences
Device name	PainFreeze II	PainFreeze	
Manufacturer	Nuance Medical, Inc.	Nuance Medical, Inc.	
Indications for Use	PainFreeze II Medium Stream and Mist Spray are vapocoolants (skin refrigerants) intended for topical application to skin,	Pain Freeze Mist Spray and Medium Stream Spray are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous	Same with the exception of removing the statement "Pain Freeze Medium Stream Spray is also intended for the

Table 10.1: Comparison Table – Subject & Predicate Devices			
Comparison Feature	**Subject Device**	**Predicate Device**	**Similarities/ Differences**
	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 (lancing boils, incisions, drainage of small abscesses, and sutures), and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions).	membranes (oral cavity, nasal passageways, and the lips) and minor open wounds. Pain Freeze controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). Pain Freeze Medium Stream Spray is also intended for the management of myofascial pain, restricted motion and muscle tension.	management of myofascial pain, restricted motion and muscle tension." This does not impact the safety and efficacy of the device.
Product Configurations	Mist spray Medium stream spray	Mist spray Medium stream spray	Same
Chemical Composition	HFO-1233zd (Trans-1-chloro-3,3,3- trifluoropropene) 60% and HFO-1234ze (trans-1,3,3,3-tetrafluoroprop-1- ene) 40%	1,1,1,3,3-Pentafluoropropane (HFC- 245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5%	The formation of the device is different. Information incorporated in the submissions demonstrates the formulation is safe and effective.
Container Size	35ml, 115ml	103.5ml	Volume offered differs, however there is no impact on safety or efficacy
Target Populations	Adults	Not Publicly Available	Safety and efficacy are not impacted.
Patient Contact	Skin	Skin	Same
Energy Delivery	Thermal energy via refrigerant spray	Thermal energy via refrigerant spray	Same
Vapocoolant Discharge Method	Handheld spray containers. Button on actuator is pressed.	Depress the Actuator Button to release the vapocoolant	Same
Boiling Point	-3.0±3°C	Not Publicly Available	A comparison evaluation was conducted, which the temperature exiting the canister is similar to the predicate. Safety and efficacy are not impacted.
Mechanism of Action & Operating Principle	Cooling by application of refrigerant; Dispensing valve on canister is depressed to release the refrigerant.	Depress the Actuator Button to release the vapocoolant	Same
Flammability	Non-flammable	Non-flammable	Same
Mechanical Safety	Mechanism has positive shut-off release	Mechanism has positive shut-off release	Same

Shelf-Life	24 months	Not Publicly Available	Shelf-life may differ; however, stability testing is conducted, which demonstrates no impact to safety and efficacy.

Storage & Transportation	Not to exceed 49°C	Not Publicly Available	Storage conditions may vary; however, restrictions are indicated on the product labeling.

Non-Clinical Testing

Assessments were performed that includes the following:

- Temperature Comparison – Evaluation demonstrated the temperature exiting from the canister is similar 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 compromised skin and a limited exposure (<24 hours). Evaluations included:
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity

  All test criteria were successfully met for each evaluation.
- Stability – The following evaluations were conducted at various assessment intervals up to the stated shelf-life limits:
    - Visual Inspection
    - Total Delivery
    - Pressure
    - Spray Rate
    - Leakage/Weight Loss
    - Microbiological

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

Results of the evaluations demonstrate that the Subject Device met the safety and performance requirements as it relates to its indication for use and the Predicate.

Clinical Testing

Not Applicable

Conclusions

The results of the evaluation demonstrate that the Subject Device is substantially equivalent to the Predicate.