October 18, 2017

Nuance Medical, LLC
Marc Lieberman
CEO
5931 Sea Lion Place, Suite 113
Carlsbad, California 92010

Re: K172203
Trade/Device Name: CryoDose TA OTC, Mist Spray and
CryoDose TA OTC, Stream Spray
Regulatory Class: Unclassified
Product Code: MLY
Dated: July 19, 2017
Received: July 21, 2017

Dear Marc Lieberman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172203

Device Name
CryoDose TA OTC (Mist Spray and Stream Spray)

Indications for Use *(Describe)*
Mist Spray:
CryoDose TA OTC is used like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions and minor sports injuries.
Stream Spray:
CryoDose TA OTC is used like ice for muscle spasm and for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions and 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.

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K172203 – 510(k) Summary

Nuance Medical, LLC – CryoDose TA^{OTC}

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

I. SUBMITTER

Owner:
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Contact Person:
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Date Prepared: October 17, 2017

II. DEVICE

Trade Name: CryoDose TA^{OTC}, Stream Spray, Model #1821
CryoDose TA^{OTC}, Mist Spray, Model #1815

Common Name: Cold Spray - 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane)

Classification Name: Refrigerant Topical, Vapocoolant

Product Code: MLY

III. PREDICATE DEVICE

Primary:
Gebauer's Instant Ice (Mist Spray & Stream Spray)
Gebauer Company.
K021726
Legally marketed medical device

Reference Device:
PainFreeze (Mist Spray & Stream Spray
Nuance Medical
K162218
Legally marketed medical device

IV. DEVICE DESCRIPTION

The predicate is a legally marketed device.

Nuance Medical's CryoDose TA^{OTC} (subject device) is an over-the-counter (OTC) device designed to deliver a standard mixture 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane), which is being offered in two delivery configurations, Mist Spray (Model No. 1815) and Stream Spray (Model No. 1821). This mixture self-propels itself from the delivery system, which is designed to account for its low vapor pressure. The device's delivery system controls the amount of the CryoDose TA^{OTC} mixture that is dispensed, the Mist Spray configuration produces very fine droplets that create cooling at the points of contact. The Stream Spray configuration produces a pinpoint stream that contacts the skin surface at a specific single location. Both configurations contain the same standard mixture thus there is not safety or effectiveness concerns between configuration. The skin is cooled through rapid evaporation of the non-medicated propellants.

CryoDose TA^{OTC}, is substantially equivalent, if not identical, to the predicate device Gebauer's Instant Ice (Mist Spray and Stream Spray). Both devices are indicated for use to provide temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sport injuries.

V. INDICATIONS FOR USE

The Indications for Use is similar to the predicate device.

Mist Spray:

> CryoDose TA^{OTC} is used like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions and minor sports injuries.

Stream Spray:

> CryoDose TA^{OTC} is used like ice for muscle spasm and for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions and minor sports injuries.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same technical characteristics as the predicate device including materials, design, and energy source. There are no technological differences between the predicate and the submitted device. Refer to the following table for the comparison between the subject device and the predicate:

Comparison Chart – Technological Characteristics			
Trade Name	Nuance Medical's CryoDose TA^{OTC} *Subject Device*	Gebauer's Instant Ice *Predicate*	Nuance Medical's PainFreeze *Reference Device*
Type	OTC	OTC	Rx
Product Design	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap
Indication for Use/ Intended Use	Mist Spray: CryoDose TA OTC is used like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions and minor sports injuries. Stream Spray: CryoDose TA OTC is used like ice for muscle spasm and for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions and minor sports injuries.	Clinical conditions that may respond to the cooling effect's of Gebauer's Instant Ice™ Mist Spray are to use like ice for temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sport injuries. For Gebauer's Instant Ice™ Stream spray they are to use like ice for the temporary relief and reduction of minor pain and swelling from sprains, strains, bruising, contusions or minor sports injuries and muscle spasms.	PainFreeze™ Mist Spray and Medium Stream Spray are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passage ways and the lips) and minor open wounds. PainFreeze™ 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). PainFreeze™ Medium Stream Spray is also intended for use the management of myofascial pain, restricted motion and muscle tension.
Product Fill Volume	3.5oz (103.5mL)	3.5oz (103.5mL)	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%	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	Thermal Energy via Refrigerant Spray
Energy Deposited	N/A	N/A	N/A
Vapocoolant Discharge Method	Depress the Actuator Button to release the vapocoolant	Depress the Actuator Button to release the vapocoolant	Depress the Actuator Button to release the vapocoolant
Environmental Compatibility	Non-Flammable	Non-Flammable	Non-Flammable
Mechanical Safety	Mechanism has positive shut-off release	Mechanism has positive shut-off release	Mechanism has positive shut-off release

Substantial Equivalence:

The predicate and reference device are legally marketed devices. The subject device has similar intended use (Indications for Use) as the predicate device. The reference device's Indications for Use is similar in that it is topically applied for temporary relief of minor sports injuries, however is also associated with injections and minor surgical procedures that is conducted by healthcare professionals. 21 CFR 807.107(b)(1)

The subject device is for Over-The-Counter (OTC) like the predicate. The reference device is the Rx version of the subject device.

The subject device has the same technological characteristics as the predicate and reference device. 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 or reference device. 21 CFR 800.107(b)(2)(i)

The subject, predicate, and reference 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.

The subject, predicate, and reference devices use the same materials, design, energy source and other features.

The subject device is a reverse-engineering of its predicate and identical to the reference device.

Differences between the subject, predicate, and reference device, if any, would be limited to discussion and promotion of product, marketing materials, and cosmetic labeling as well as the reference device is for prescription use while the subject device and predicate are OTC.

The subject device does not raise questions of safety and effectiveness efficacy different from the predicate or the reference device.

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 are substantially equivalent to the predicate.

Summary: CryoDose TA^{OTC} is substantially equivalent and no technological differences exist to the predicate device. 21 CFR 800.107(b)(2)(i)

VII. PERFORMANCE DATA

The subject, predicate, and reference devices use the same materials, design and energy source and no technological differences exist. Tests were selected and performed to ensure the subject device's output performance are the same as its predicate. The following tests were performed in support of substantial equivalence:

Biocompatibility

Since the reference device is identical to the subject device's composition and indication for use, the biocompatibility results of the reference device were utilized. The subject/reference

device is categorized as a surface-contacting/breached or compromised surface with limited contact duration (≤ 24 hours). The biocompatibility test program is based on ISO 10993-1:2009, which the following evaluations were conducted:

- Cytotoxicity (ISO 10993-5: 2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

Biocompatibility testing met each evaluation's acceptance requirements, which demonstrated the material's safety.

Chemical Composition Confirmation

The subject device and predicate 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 predicate.

Structural and Parts Composition

Since the reference device is identical to the subject device's construction, engineering verification results for the reference device were utilized. Engineering verification measurements were taken and visual inspections were made to determine the canisters, valves, and caps were equivalent to the predicate.

Directions for Use (Clinical Use) Application and Methodology:

All key elements of the Directions for Use (DFU) between the predicate and the subject device are equivalent including indication for use, intended use, precaution statements, warning statements, and contraindication statements, and treatment regiment. No substantial differences exist between the predicate and subject device's Directions for Use.

Side-by-Side Temperature & Output Bench Testing

Since the reference device is identical to the subject device's construction and composition, the performance results for the reference device were utilized. 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 is 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 as it relates to the subject device, as compared to the predicate, it was found to be safety and effectiveness and similar, if not identical, to the predicate. The following was demonstrated for substantial equivalence:

- Material safety through biocompatibility

- Identical chemical composition
- Identical canister volume and construction
- Identical clinical use, application and methodology
- Equivalent temperature at application surface and volume dispersed from canister

VIII. CONCLUSION

Based on the information provided in the submission, it is concluded that the CryoDose TA^{OTC} is safe and effective for its intended use and has demonstrated substantially equivalent to the predicated device.