DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 12, 2016

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

Re: K161337
Trade/Device Name: CryoDose H
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 7, 2016
Received: May 13, 2016

Dear Mr. 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 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 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 yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K161337

Device Name
CryoDose H

Indications for Use *(Describe)*

The CryoDose H indications for use as follows: CryoDose H is indicated for use in the treatment of actinic keratosis, genital warts, lentigo, mulluscum contagiosum, seborrheic keratosis, skin tags, verruca plantaris, verruca vulgaris, and verruca plana.

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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"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."

5. 510(k) Summary

Nuance Medical, LLC – CryoDose H

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

I. SUBMITTER

Owner: Nuance Medical, LLC.
5931 Sea Lion Place, Suite 113
Carlsbad, CA 92010
(760) 585-4849

Contact Person: Marc S. Lieberman
Nuance Medical, LLC.
5931 Sea Lion Place, Suite 113
Carlsbad, CA 92010
760-585-9548 (Direct)

Date Prepared: May 7, 2016

II. DEVICE

Name of Device: CryoDose H

Common Name: Cryogen Spray:
Dimethyl Ether, Propane, Isobutane

Classification Name: Unit, Cryosurgical Accessories (21CFR 878.4350)

Product Code: GEH

III. PREDICATE DEVICE

Primary: Histofreezer
Orasure Technologies, Inc.
K990877
Legally marketed medical device
This predicate has not been subject to a design-related or other recall.

References: As a reference for the reviewer, other predicate devices utilizing the identical ingredients (95% dimethyl ether, 2% propane, 3% isobutane) or similar ingredients and cleared by the FDA include: Histofreezer (K911420, K924114, and K971392), Histofreezer (K023487-OTC), CryoNize (K103310), Dr. Scholl's Freeze Away (K031697 - OTC), Wartner Wart Removal (K011708 - OTC).

IV. DEVICE DESCRIPTION

The predicate is a legally marketed device.

The proposed device, CryoDose H, is used in the practice of dermatology in the treatment of benign skin lesions using a cryogen spray system. The device consists of an aerosol-filled canister and parts within the canister. The canister is sold within a kit with accessories including: Directions for Use, swabs, and packaging materials.

The treatment methodology is simple and has remained virtually unchanged for decades. The aerosol is sprayed onto a foam covered cotton swab that is then placed upon the benign lesion (e.g. wart) for 15-40 seconds. This procedure is used and accepted by physicians using commonly accepted procedures and techniques. It utilizes a decades-old, standard cryogen composition profile to freeze common skin lesions.

V. INDICATIONS FOR USE

The Indications for Use is identical to the predicate device.

The CryoDose H indications for use as follows: CryoDose H is indicated for use in the treatment of the following:

- actinic keratosis
- genital warts
- lentigo
- mulluscum contagiosum
- seborrheic keratosis
- skin tags
- verruca plantaris
- verruca vulgaris
- verruca plana

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed 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.

The cryogen used in the proposed device, CryoDose H, is dimethyl ether (95%), propane (2%), isobutane (3%) is identical in chemical composition and formulation as the predicate device, Histofreezer.

All other elements of CryoDose H have the same technical characteristics as the predicate device including:

- Canister
- Valve
- Actuator
- Cover Cap
- Foam Tipped Swabs

The method for delivering the cryogen is identical to the predicate.

Substantial Equivalence:

The predicate device, Histofreezer is a legally marketed device. The proposed device (CryoDose H) has the same intended use (Indications for Use) as the predicate device (Histofreezer). CFR 800.100(b)(1)

The proposed device (CryoDose H) has the same technological characteristics as the predicate device (Histofreezer). 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 device. CFR 800.100(b)(2)(i)

The proposed device and the predicate device use an identical (substantially equivalent) chemical composition by type and percent of components: dimethyl ether (95%), propane (2%), and isobutane (3%).

The proposed device and the predicate device use the same design, energy source, materials, and other features. When the liquid is dispensed, it saturates the foam tip. The foam tip is then applied directly to the desired area of treatment. Subsequently, the thermal energy is removed from the freezing of the skin lesion. Kits include a canister filled with the cryogen and foam tip applicators.

Differences, if any, would be limited to discussion and promotion of product, marketing materials, cosmetic labeling, etc. only.

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

Labeling:

The labeling of CryoDose H has been prepared to ensure the medical professional has adequate and clear instructions for safety and usage. It includes canister labeling, instructions for use, safety and warning statements and are substantially equivalent to the predicate.

Thus, CryoDose H is substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

Tests were performed to ensure the proposed device's output performance was substantially similar to the predicate.

Biocompatibility Testing

Biocompatibility testing was performed on all patient contact device accessories: the foam tipped swab applicators to ensure that the finished device is biocompatible. Studies were conducted based on the requirements of ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The battery of test included cytotoxicity, sensitization and irritation. The foam tip swab applicators are categorized and were tested as an external, short term contact with the skin (< 24 hours).

Chemical Composition Confirmation

Both systems use identical aerosols profiles: dimethyl ether (95%), propane (2%), and isobutane (3%). The proposed 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

Engineering verification measurements were taken and visual inspections were made to determine the canisters, valves, and caps were identical or substantially equivalent between the predicate and the proposed device.

Instructions for Use (Clinical Use) Application and Methodology:

Side-by-side Instructions for Use from the predicate device and the proposed device clinical use and product claims made to determine substantial equivalence. No substantial differences exist between the predicate and proposed device's Instructions for Use.

Side-by-Side Temperature Bench Testing

Comparative Cryogen Performance testing was conducted to determine the output temperature of the predicate and proposed devices. The output temperature was measured in three tests: (1) the output nozzle exit of the cryogen from the canister, (2) the cryogen-saturated applicator foam tips, and (3) visual confirmation for "ice ball" on neoprene-backed practice pads. Practical tests assessments to determine substantial equivalence were conducted.

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 conducted under controlled conditions at room temperature and under accelerated conditions.

Summary

Based on the testing performance conducted the proposed device, CryoDose H, was found to have a safety and effectiveness profile that is similar, if not identical, to the predicate device, Histofreezer.

VIII. CONCLUSION

Based on the information presented above and within this submission, it is concluded that the CryoDose H is safe and effective for its intended use and is substantially equivalent to the predicated device. Also, the labeling is substantially equivalent to the predicate device.