October 22, 2021

Nuance Medical, Inc.
Mr. Neal Hartman
Regulatory Affair/Quality Assurance
5931 Sea Lion Place, Suite 113
Carlsbad, California 92010

Re: K210310
Trade/Device Name: CryoDose V50/50
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: October 8, 2021
Received: October 12, 2021

Dear Mr. 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 (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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K210310

Device Name
CryoDose V 50/50

Indications for Use *(Describe)*
For the treatment of verruca (warts) including plantar warts, sehorrheic keratoses, actinic keratosis, achrochorodon, molluscum, contagiosum, age spots, dermatofibroma, small keltoids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chrondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyrogenic granualpma.

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."

Nuance Medical

510(K) SUMMARY

Submitter Information

Company Name:	Nuance Medical, Inc.
Company Address:	Nuance Medical, Inc. 5931 Sea Lion Place, Suite 113 Carlsbad, CA 92010
Company Phone:	(760) 585-9548
Company Facsimile:	(760) 235-4572
Contact Person No. 1:	Marc S. Lieberman Chief Executive Officer marc@cryodose.com
Contact Person No. 2:	Neal Hartman Regulatory Affairs/ Quality Assurance 892 Summer Moon Road San Marcos, CA 92078 858.382.6550 nealenhartman@gmail.com
Date:	October 16, 2021

Device Identification

Device Trade Name:	CryoDose $V_{50/50}$
Common Name:	Cryogen Spray
Classification Name(s):	Cryosurgical unit and accessories
Regulation(s):	878.4350
Device Class:	Class II
Product Code(s):	GEH
Advisory Panel:	General & Plastic Surgery

Identification of Predicate Devices

The System Device is substantially equivalent to the following device:

Device Name	Classification Regulation	Product Code	510(K) Number	Clearance Date
Nuance Freeze Spray System	878.4350 - Cryosurgical unit and accessories	GEH	K130995	6/14/2013

Device Description

The Subject Device is used in the practice of dermatology in the treatment of skin lessons using a cryogen spray system. This methodology is an accepted practice used by physicians for decades using accepted procedures and techniques. It utilizes a cryogen composition profile to freeze common skin lessons that is has a lower global warming potential then the predicate device and is safe and provide equivalent performance.

The chemical composition is a blend of HFC-32 and HFO-1234ze. HFC-32, difluoromethane, is a colorless gas typically used as a refrigerant. HFO-1234ze, trans-1,3,3,3-tetrafluoroprop-1-ene, is a colorless gas and a new generation hydrofluoroolefin developed for its low global warming potential.

Indications for Use

For the treatment of verruca (warts) including plantar warts, seborrheic keratoses, actinic keratosis, achrochorodon, molluscum, contagiosum, age spots, dermatofibroma, small keltoids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chrondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyrogenic granuloma.

Comparison of Technological Characteristics with Predicate and Reference Devices

Comparison Feature	Subject Device	Predicate Device
Device name	CryoDose $V_{50/50}$	Nuance Freeze Spray System
Manufacturer	Nuance Medical, Inc.	Nuance Medical, Inc.
Indications for Use	For the treatment of verruca (warts) including plantar warts, seborrheic keratoses, actinic keratosis, achrochorodon, molluscum, contagiosum, age spots, dermatofibroma, small keltoids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chrondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyrogenic granuloma.	1,1,1,2-tetrafluoroethane, pentafluoroethane, and 1,1,1-trifluorethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratoses, actinic keratosis, achrochorodon, molluscum, contagiosum, age spots, dermatofibroma, small keltoids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chrondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyrogenic granuloma.
Target Population	Adults	Adults
Anatomical Sites	Skin	Skin
Chemical Name	HFC-32/HFO-1234ze Blend	HFC blend (R-404a)
Chemical Composition	difluoromethane (50%) trans-1,3,3,3-tetrafluoroprop-1-ene (50%)	1,1,2-tetrafluoroethane (4%) pentafluoroethane (44%) 1,1,1-trifluoroethane (54%).
Molecular Weight	97.6	71.4
Bolling Point	-47.8°C	-46.2°C
Liquid Density @ 25°C	~1.13 g/cc	1.05 g/cc
Heat of Vaporization	~233 kj/kg	202.1 kj/kg
Global Warming Potential (CO_2=1)	~340	3260
Flammability	Non-flammable	Non-flammable

Comparison Feature	Subject Device	Predicate Device
Mechanism of Action	Freezing by application of cryogen	Freezing by application of cryogen
Application Method	Handheld spray cannister with applicators	Handheld spray cannister with applicators
Temperature at application site @ 3- & 7-seconds spray /3" distance	Surface: -60°C Subcutaneous -5°C Intramuscular: 30°C	Surface: -60°C Subcutaneous -5°C Intramuscular: 30°C
Temperature at application site @ 7 seconds spray/ 6" distance	Surface: -60°C Subcutaneous -5°C Intramuscular: 28°C	Surface: -65°C Subcutaneous -8°C Intramuscular: 32°C
Spray weight with 5 second spray	0.015 lb.	0.015 lb.
Mechanical Safety	Positive shut-off release	Positive shut-off release
Cannister Fill Size	175, 236 ml	162, 236 ml
Kit Components	Device cannister, Cones, Swabs	Device cannister, Cones, Swabs
EMI Radiation Safety	N/A	N/A

Technically, the Subject Device has similar mechanical properties to the predicate as well as its performance. The same patient population and use indications applies between the devices. Identical cannister components and applicators are used with both devices. The main differences between the Subject Device and predicate is that the global warning potential is significantly less with the Subject Device. The differences in the Subject Device does not impact safety, effectiveness, or performance.

Summary of Testing Performed

Assessments were performed that includes the following:

- Temperature
- Flammability/Ignition
- Spray Rate
- Pressure
- Visual Freezing

As indicated in the above comparison chart, the Subject Devices in non-flammable, deliveries similar temperatures at the application site, and the spray weight is identical than that of the predicate.

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

Conclusions Drawn from Nonclinical Evaluation

The results of the evaluation demonstrate that the Subject Device is substantially equivalent to the predicate as it pertains to the indications for use and device performance.