5. 510(k) Summary

JUN 14 2013

Nuance Medical, LLC – Nuance Freeze Spray System

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

Owner's Name and Address:		Nuance Medical, LLC 300 Carlsbad Village Drive, Suite 108 Carlsbad, CA 92008 (760) 525-4032
Contact Information:		Marc S. Lieberman Nuance Medical, LLC 300 Carlsbad Village Drive, Suite 108 Carlsbad, CA 92008 (760) 525-4032
Date Prepared:		June 14, 2013
Device Trade Name:		Nuance Freeze Spray System
Common Name:		Cryogen Spray: 1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1-trifluoroethane or R-404a
Classification Name:		Class II - "Unit, Cryosurgical Accessories" (Regulation 21CFR 878.4350; Product Code: GEH)
Predicate Devices:	**Primary:**	Cryosurgery, Inc. Verruca-Freeze Cryosurgery Delivery System K982506
	Secondary:	Cryosurgery, Inc. Verruca-Freeze Cryosurgery Delivery System K881349
	Secondary:	Cryosurgery, Inc. Verruca-Freeze Cryosurgical Delivery System K944221

Description of the Device:

The Nuance Freeze Spray System is used in the practice of dermatology in the treatment of skin lesions using a cryogen spray system. This methodology is an accepted practice used by physicians for decades using accepted procedures and techniques. It utilizes a standard cryogen composition profile to freeze common skin lesions.

Indications for Use:

The Nuance Freeze Spray System indications for use as follows:
1,1,1,2-tetrafluoroethane, pentafluoroethane, and 1,1,1-trifluoroethane 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 pyogenic granuloma.

Technical Characteristics:

The cryogen used in the Nuance Freeze Spray System is 1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1-trifluoroethane also commonly known as R-404a and is produced as a standard formulation by numerous chemical companies. Nuance Medical is using the exact same chemical composition and formulation as the predicate device. All other characteristics of the Nuance System are designed to be identical or nearly identical as the predicate device. The methods for delivering the cryogen are similar to the predicate.

Substantial Equivalence:

Nuance Freeze Spray System and its predicate devices are all devices that are used for the treatments of skin lesions using cryogen with the same chemical composition by type and percent of components: **1,1,2-tetrafluoroethane (4%), Pentafluoroethane (44%), and 1,1,1-trifluoroethane (54%)**. Differences in the technological characteristics are negligible and would be limited to discussion and promotion of product, marketing materials, cosmetic labeling, etc. Nuance Freeze Spray System and its predicate devices do not raise any new issues of safety or efficacy. Thus, Nuance Freeze Spray System is substantially equivalent to the predicate devices for treatment of certain skin lesions outlined in the indications for use.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Nuance Medical, LLC
% Marc S. Lieberman
President and CEO
300 Carlsbad Village Drive, Suite 108
Carlsbad, California 92008

June 14, 2013

Re: K130995
Trade/Device Name: Nuance Freeze Spray System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: April 06, 2013
Received: April 16, 2013

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.

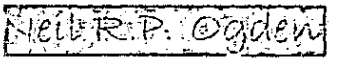
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



For Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Statement of Indications for Use

510(k) Number (if known): K130995

Device Name: Nuance Freeze Spray System

Indications for Use: 1,1,1,2-tetrafluoroethane, pentafluoroethane, and 1,1,1-trifluoroethane 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 pyogenic granuloma.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off)
Division of Surgical Devices (DSD)
510(k) Number K130995