December 4, 2023

CryoSurgery, Inc.
℅ Rachel Paul
Lead Consultant QA&RA
Emergo Europe Consulting
Prinsessegracht 20
The Hague, 2514AP
Netherlands

Re: K233347
Trade/Device Name: Verruca-Freeze® H
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 29, 2023
Received: September 29, 2023

Dear Rachel Paul:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.12.04 08:24:35 -05'00'

Mark Trumbore, 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)*

K233347

Device Name

Verruca-Freeze® H

Indications for Use *(Describe)*

The Verruca-Freeze® H cryosurgical system is indicated for use in the treatment of the following skin lesions:
- Actinic Keratosis
- Genital Warts
- Lentigo
- Molluscum Contagiosum
- Seborrheic Keratosis
- Skin Tags
- Verruca Plantaris
- Verruca Vulgaris
- 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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510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

1. Submitter Information

Company:	Ronald A. McDow, MD Medical Director CryoSurgery, Inc. 5829 Old Harding Pike Nashville, TN 37205 USA Telephone: (615) 354-0414 Fax: (615) 354-0466 rmcdow@comcast.net
Contact:	Rachel Paul Lead Consultant QA&RA Emergo Europe Consulting Prinsessegracht 20 The Hague, 2514AP The Netherlands Telephone: + 31 (0) 70 345 85 70/Direct: + 31 (0) 70 850 82 49 Fax: LST.AUS.ProjectManagement@ul.com
Date Summary Prepared:	November 27, 2023

2. Name of the Device

Trade Name:	Verruca-Freeze® H
Common Name:	Unit, Cryosurgical, Accessories
Classification Name:	General & Plastic Surgery
Review Panel:	General & Plastic Surgery (SU)
Regulation:	878.4350
Class:	Class II
Product Code:	GEH

3. Equivalence Claimed to Predicate Device

The Verruca-Freeze® H is equivalent to the CryoDose H Or Similar (K161337), manufactured by Nuance Medical, LLC.

4. Device Description

The Verruca-Freeze® H cryosurgical system is used for treatment of benign skin lesions.

The device consists of:

- Canister filled with a liquid mixture of the compressed gases dimethyl ether, propane, and isobutane
- Polyurethane foam swabs
- Detailed instructions including illustrated descriptions

The main component of the device is the pressurized aerosol canister containing cryogen spray. The canister is used with foam swabs, which are non-sterile, single-use applicators that are disposed after each use. The foam swabs allow the cryogen to be localized to a target lesion.

The one- to two-minute procedure begins by spraying cryogen onto a foam swab, which is then placed directly onto the lesion and held for 15-40 seconds. Upon removal of the swab from the skin, the frozen tissue appears white and begins thawing. The typical thaw time is 20-40 seconds.

This treatment methodology is simple and has been an accepted practice used by physicians for decades. It utilizes a standard cryogen composition profile to freeze lesions and destroy the underlying tissue through evaporative cooling. On the cellular level, both extracellular and intracellular ice formation are occurring.

5. Substantial Equivalence Comparison

Substantial Equivalence Table		
Characteristic	**Proposed Device: Verruca-Freeze® H**	**Primary Predicate Device: CryoDose H Or Similar (K161337)**
Intended Use	The Verruca-Freeze H cryosurgical system is used for treatment of benign skin lesions.	The CryoDose H is used for treatment of benign skin lesions.

Indication for Use	The Verruca-Freeze H cryosurgical system is indicated for use in the treatment of the following skin lesions: Actinic Keratosis, Genital Warts, Lentigo, Molluscum Contagiosum, Seborrheic Keratosis, Skin Tags, Verruca Plantaris, Verruca Vulgaris, and Verruca Plana	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, molluscum contagiosum, seborrheic keratosis, skin tags, verruca plantaris, verruca vulgaris, verruca plana
Product Code	GEH	GEH
Regulation Number	878.4350	878.4350
Classification Name	Unit, Cryosurgical, Accessories	Unit, Cryosurgical, Accessories
Mechanism of Action	Application of extreme cold causing tissue destruction	Application of extreme cold causing tissue destruction
Cryogen Gas Material	Dimethyl Ether (95%), Propane (2%) and Isobutane (3%)	Dimethyl Ether (95%), Propane (2%) and Isobutane (3%)
Freeze Time	15-40 seconds	15-40 seconds
Applicators	Foam swabs	Foam swabs
Sterile	No	No
OTC or Rx	Rx	Rx
Design	Aerosol-filled canister and parts within the canister (valve, actuator, cover cap)	Aerosol-filled canister and parts within the canister (valve, actuator, cover cap)
Freezing temperature	-50°C	-50°C
Shelf life	2-year	2-year

6. Additional Information

6.1 Substantial Equivalence Discussion

The technological characteristics of Verruca-Freeze® H, including materials, design, and energy source, are identical to the predicate device. The table as above compares Verruca-Freeze® H to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence.

Other elements of Verruca-Freeze® H not mentioned in the table that have the same technical characteristics as the predicate device include:

- Canister
- Valve
- Actuator
- Cover Cap

Verruca-Freeze® H has the same technological characteristics as the predicate device. Both devices use the same design, energy source, materials, and other features. When the cryogen is dispensed, it saturates the foam swab. The foam swab is then applied directly to the desired area of treatment. Subsequently, the skin lesion is frozen and destroyed. Verruca-Freeze® H does not raise any new questions of safety or effectiveness as compared to the predicate device.

It is concluded that Verruca-Freeze® H is substantially equivalent to the predicate device.

6.2 Non-Clinical Performance Data

Performance testing was conducted to determine the output temperature and effectiveness of Verruca-Freeze® H as compared to the predicate device. The output temperature was measured in the cryogen-saturated foam-tipped applicators followed by a visual confirmation of an "ice ball" on a neoprene pad. The tests determined that Verruca-Freeze® H cryogen and applicators perform equivalently to the cryogen and applicators of the predicate device. Further, the tests demonstrated that the device is capable of reaching the minimum required temperature to destroy the underlying tissue of a skin lesion.

6.3 Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use are equivalent to those of the predicate device. These types of devices have been on the market for decades and their clinical safety and efficacy has been established. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

7. Substantial Equivalence Conclusion

Based on the device characteristics and testing, the Verruca-Freeze® H is substantially equivalent to the predicate device and raises no new questions related to safety or effectiveness.