December 3, 2024

CryoSurgery, Inc.
Dr. Ronald McDow
CEO and Medical Director
5829 Old Harding Pike
Nashville, Tennessee 37205

Re: K243454
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: November 7, 2024
Received: November 7, 2024

Dear Dr. Ronald McDow:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.12.03 07:38:42 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243454

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.

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."

510(k) #: K243454

510(k) Summary

Prepared on: 2024-11-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CryoSurgery, Inc.
Applicant Address	5829 Old Harding Pike Nashville TN 37205 United States
Applicant Contact Telephone	615-354-0414
Applicant Contact	Dr. Ronald McDow
Applicant Contact Email	info@cryosurgeryinc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Verruca-Freeze H
Common Name	Cryosurgical unit and accessories
Classification Name	Unit, Cryosurgical, Accessories
Regulation Number	878.4350
Product Code(s)	GEH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233347	Verruca-Freeze H	GEH

Device Description Summary

21 CFR 807.92(a)(4)

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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the same indications for use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device. Both devices use the same design, energy source, materials, and other features.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

A stability protocol was developed to ensure that the the product is maintained throughout its labeled dating period. Testing conducted under controlled conditions at room temperature and under accelerated conditions.