March 13, 2025

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

Re: K243487
Trade/Device Name: CryoFreeze Wart and Skin Tag Remover
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 12, 2025
Received: February 12, 2025

Dear 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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.03.13 11:38:50 -04'00'

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.

510(k) Number *(if known)*
K243487

Device Name
CryoFreeze Wart and Skin Tag Remover

Indications for Use *(Describe)*
The CryoFreeze Wart and Skin Tag Remover is intended for use in the over-the-counter treatment of common warts and plantar warts in adults and children age 4 years or older and over-the-counter treatment of skin tags in adults age 22 years or older.

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.

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510(k) Summary

1. Submission Sponsor

CryoSurgery, Inc.
5829 Old Harding Pike
Nashville, TN 37205
(615) 354-0414
info@cryosurgeryinc.com

2. Contact Person

Ronald McDow
5829 Old Harding Pike
Nashville, TN 37205
(615) 354-0414

3. Date Prepared

Updated 03/07/2025

4. Device Identification

Trade / Proprietary Name	CryoFreeze Wart and Skin Tag Remover
Common / Used Name	OTC Cryosurgical Device
Regulation	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

5. Predicate Device

Device Name	Freeze 'n Clear Skin Clinic for Warts and Skin Tags
510(k) Number	K211099
Regulation Number	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

6. Reference Device

Device Name	Verruca-Freeze H
510(k) Number	K243454
Regulation Number	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

7. Description of the Subject Device

The CryoFreeze Wart and Skin Tag Remover is an over-the-counter (OTC) cryotherapy device designed for the treatment of common, plantar warts, and skin tags. The device includes:

- A pressurized aerosol canister filled with a liquid mixture of the compressed gases dimethyl ether, propane, and isobutane
- Applicator swabs
- Detailed instructions, including illustrated descriptions

To use the device, the user must insert an applicator swab into the actuator, saturate the swab with cryogen, and apply the foam tip of the swab directly onto the lesion, holding it in place for 40 seconds. After removal, the frozen tissue will appear white and begin to thaw, typically taking 20-40 seconds.

The device is non-sterile and intended for home use by laypersons. No special training or sterilization is required for operation.

8. Indications for Use

The CryoFreeze Wart and Skin Tag Remover is intended for the over-the-counter treatment of common warts and plantar warts in adults and children age 4 years or older and over-the-counter treatment of skin tags in adults age 22 or older.

9. Technological Comparison

The subject device has the same technological characteristics as the predicate device. It shares the same intended use, mechanism of action, and design as the predicate device.

Additionally, the subject device has the same technological characteristics, mechanism of action, design as the reference device Verruca-Freeze H.

Technological Characteristics	**Subject Device:** CryoFreeze Wart and Skin Tag Remover	**Predicate Device:** Freeze 'n Clear Skin Clinic for Warts and Skin Tags
Trade Name / Device Name	CryoFreeze™ Wart and Skin Tag Remover	Skin Clinic Freeze 'n Clear for Warts and Skin Tags
510(k) Number	K243487	K211099
Indications for Use	The CryoFreeze Wart and Skin Tag Remover is intended for use in the over-the-counter treatment of common warts and plantar warts in adults and children age 4 years or older and over-the-counter treatment of skin tags in adults age 22 years or older.	The Freeze n' Clear Skin Clinic for Warts and Skin Tags product is intended for OTC treatment of common warts, plantar warts, and skin tags.
Cryogen Material	Mixture of dimethyl ether, propane, and isobutane	Mixture of dimethyl ether, propane, and isobutane
Freeze Temperature	-55°C	-55°C
Design	-Cryogen canister with attached safety shield -Foam-tipped applicators -Disposable tweezers	-Cryogen canister with attached safety shield -Foam-tipped applicators -Disposable tweezers
Mechanism of Action	Extreme cold destroys the target tissue	Extreme cold destroys the target tissue

Treatment Procedure	Cryogen is dispensed into foam applicator which is then applied to the lesion for a specified number of seconds.	Cryogen is dispensed into foam applicator which is then applied to the lesion for a specified number of seconds.
Storage and Safety Conditions	-Keep away from fire or flame -Do not smoke while using the product -Do not puncture or incinerate canister -Do not expose to heat or store at temperatures above 120°F. -Store at room temperature away from heat	-Keep away from fire or flame -Do not smoke while using the product -Do not puncture or incinerate canister -Do not expose to heat or store at temperatures above 120°F. -Store at room temperature away from heat
Disposal	Entire unit is disposable after emptied of cryogen.	Entire unit is disposable after emptied of cryogen.
Defined Operators	OTC for consumer use	OTC for consumer use

10. Non-Clinical Performance Data

CryoFreeze Wart and Skin Tag Remover underwent comparative performance testing against the reference device, Verruca-Freeze H. The tests included output temperature of cryogen, freeze charge hold time, and visual confirmation of the ice ball. The comparison of test data confirmed that the subject device performs equivalently to the reference device.

11. Statement of Substantial Equivalence

Based on the information presented, it is concluded that the CryoFreeze Wart and Skin Tag Remover device is substantially equivalent to the predicate device Freeze 'n Clear Skin Clinic for Warts and Skin Tags.