October 10, 2025

CryoSurgery, Inc.
Kaitlyn Clements
Regulatory Affairs Coordinator
5829 Old Harding Pike
Nashville, Tennessee 37205

Re: K252903
Trade/Device Name: Verruca-Freeze H Plus
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 9, 2025
Received: September 11, 2025

Dear Kaitlyn Clements:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.10 14:35:11 -04'00'

Colin Kejing Chen
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252903

Please provide the device trade name(s).

Verruca-Freeze H Plus

Please provide your Indications for Use below.

The Verruca-Freeze H Plus cryosurgical system is intended for use by trained medical professionals to treat the following benign skin lesions:
- Actinic Keratosis
- Genital Warts
- Lentigo
- Molluscum Contagiosum
- Seborrheic Keratosis
- Skin Tags
- Verruca Plantaris
- Verruca Vulgaris
- Verruca Plana

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

1. Submission Sponsor

Ronald McDow
CryoSurgery, Inc.
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(615) 354-0414
info@cryosurgeryinc.com

2. Primary Correspondent

Kaitlyn Clements
5829 Old Harding Pike
Nashville, TN 37205

3. Date Prepared

08/27/2025

4. Device Identification

Trade / Proprietary Name	Verruca-Freeze® H Plus
Common / Used Name	Prescription Cryosurgical Device
510(k) Number	K252903
Regulation	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

5. Primary Predicate Device

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

6. Predicate Device

Device Name	Nuance Freeze Spray System
510(k) Number	K130995
Regulation Number	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

7. Reference Device

Device Name	Verruca-Freeze® H
510(k) Number	K233347

Regulation Number	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

8. Description of the Subject Device

The main component of the Verruca-Freeze® H Plus cryosurgical system 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 of after each use. The foam swabs allow the cryogen to be localized to a target lesion.

The procedure begins by saturating a foam swab with cryogen and then placing it directly onto the lesion 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 cryogen formulation to freeze lesions and destroy the underlying tissue through evaporative cooling. On the cellular level, both extracellular and intracellular ice formation occur. This submission includes a modification to the cryogen formulation. No other changes were made to the device design, intended use, or operating principle.

9. Indications for Use

The Verruca-Freeze® H Plus 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

10. Technological Comparison

A summary comparison of technological characteristics for the subject device vs predicate devices is provided in the following table:

Characteristic	Subject Device Verruca-Freeze H Plus	Predicate Device Verruca-Freeze H	Predicate Device Nuance Freeze Spray
Device Name	Verruca-Freeze® H Plus	Verruca-Freeze® H	Nuance Freeze Spray System
510(k) Number	**K252903**	**K243454**	**K130995**
Type of Use	Rx	Rx	Rx

Indications for Use	Treatment of benign skin lesions, including: •Actinic Keratosis •Genital Warts •Lentigo •Molluscum Contagiosum •Seborrheic Keratosis •Skin Tags •Verruca Plantaris •Verruca Vulgaris •Verruca Plana	Treatment of benign skin lesions, including: •Actinic Keratosis •Genital Warts •Lentigo •Molluscum Contagiosum •Seborrheic Keratosis •Skin Tags •Verruca Plantaris •Verruca Vulgaris •Verruca Plana	Treatment of skin lesions, including: •Verruca (warts), including plantar warts •Seborrheic keratoses •Actinic keratosis •Acrochordon (skin tags) •Molluscum contagiosum •Age spots •Dermatofibroma •Small keloids •Granuloma annulare •Porokeratosis plantaris •Angiomas •Keratoacanthoma •Chondrodermatitis •Epithelial nevus •Leukoplakia •Granuloma pyogenicum •Pyogenic granuloma
Product Code	GEH	GEH	GEH
Regulation Number	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350
Classification Name	Unit, Cryosurgical, Accessories	Unit, Cryosurgical, Accessories	Unit, Cryosurgical, Accessories
Device Design	Pressurized aerosol canister with valve, actuator, and foam swabs	Pressurized aerosol canister with valve, actuator, and foam swabs	Pressurized aerosol canister with valve, actuator, foam swabs, and isolation funnels
Mechanism of Action	Application of extreme cold causing tissue destruction	Application of extreme cold causing tissue destruction	Application of extreme cold causing tissue destruction
Swab Types	Arrow (2 mm), Round (5 mm)	Arrow (2 mm), Round (5 mm)	Arrow (2 mm), Round (5 mm)
Sterility	Non-sterile	Non-sterile	Non-sterile

11. Non-Clinical Performance Data

Non-clinical bench testing was conducted to evaluate the performance of the modified formulation. Testing methods were consistent with those used in the reference device's submission and included:

- Temperature of Cryogen
- Freeze Charge Hold Time
- Ice-Ball Formation

All acceptance criteria were met. The modified cryogen formulation performed as intended and is substantially equivalent to the predicate.

12. Statement of Substantial Equivalence

The Verruca-Freeze® H Plus cryosurgical system is substantially equivalent to the predicate device (K243454). The modification does not change the device's intended use, indications, or technological characteristics other than the cryogen formulation. The change to the formulation does not introduce new risks or affect safety or effectiveness. Verification and validation activities demonstrate that the modified device meets all acceptance criteria and continues to perform as intended.