



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

October 16, 2025

Re: K253000

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: September 16, 2025  
Received: September 18, 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](mailto: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: 2025.10.16  
11:08:36 -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.

K253000

?

Please provide the device trade name(s).

?

CryoFreeze Wart and Skin Tag Remover

Please provide your Indications for Use below.

?

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

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  
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info@cryosurgeryinc.com
- 2. Primary Correspondent** Kaitlyn Clements  
5829 Old Harding Pike  
Nashville, TN 37205  
kclements@cryosurgeryinc.com
- 3. Date Prepared** 10/15/2025
- 4. Device Identification**
- |                          |  |
|--------------------------|--|
| Trade / Proprietary Name | CryoFreeze Wart and Skin Tag Remover         |
| Common / Used Name       | OTC Cryosurgical Device                      |
| 510(k) Number            | K253000                                      |
| Regulation               | 878.4350 - Cryosurgical unit and accessories |
| Product Code             | GEH  |
| Class                    | 2  |
- 5. Predicate Device**
- |                   |  |
|-------------------|--|
| Device Name       | CryoFreeze Wart and Skin Tag Remover         |
| 510(k) Number     | K243487                                      |
| Regulation Number | 878.4350 - Cryosurgical unit and accessories |
| Product Code      | GEH  |
| Class             | 2  |
- 6. Predicate Device**
- |                   |  |
|-------------------|--|
| Device Name       | Skin Clinic Nitro Clear                      |
| 510(k) Number     | K242932                                      |
| Regulation Number | 878.4350 - Cryosurgical unit and accessories |
| Product Code      | GEH  |
| Class             | 2  |
- 7. Predicate Device**
- |             |                                    |
|-------------|------------------------------------|
| Device Name | Oystershell Pixie Skin Tag Remover |
|-------------|------------------------------------|

510(k) Number	K240226
Regulation Number	878.4350 - Cryosurgical unit and accessories
Product Code	GEH
Class	2

**8. 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 warts, plantar warts, and skin tags. The device includes:

- A pressurized aerosol canister filled with a liquid mixture of compressed gases
- 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.

**9. 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.

**10. Technological Comparison**

The modified CryoFreeze Wart and Skin Tag Remover cryosurgical device has the same technological characteristics as the predicate device, CryoFreeze Wart and Skin Tag Remover (K243487), with the exception of a modification to the cryogen formulation. Both devices have the same design, principle of operation, mode of use, actuator and valve system, applicator materials, packaging configuration, and labeling.

<b>Characteristic</b>	<b>Subject Device:</b> CryoFreeze Wart and Skin Tag Remover	<b>Predicate Device:</b> CryoFreeze Wart and Skin Tag Remover	<b>Comparison</b>
<b>Trade Name / Device Name</b>	CryoFreeze Wart and Skin Tag Remover	CryoFreeze Wart and Skin Tag Remover	Same
<b>510(k) Number</b>	K253000	K243487	n/a
<b>Indications for Use</b>	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	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	Same

	over-the-counter treatment of skin tags in adults age 22 years or older.	over-the-counter treatment of skin tags in adults age 22 years or older.	
<b>Type of Use</b>	Over-the-counter	Over-the-counter	Same
<b>Design</b>	<ul style="list-style-type: none"> <li>• Cryogen canister with attached safety shield</li> <li>• Foam-tipped applicators</li> <li>• Disposable tweezers</li> </ul>	<ul style="list-style-type: none"> <li>• Cryogen canister with attached safety shield</li> <li>• Foam-tipped applicators</li> <li>• Disposable tweezers</li> </ul>	Same
<b>Mechanism of Action</b>	Extreme cold destroys the target tissue	Extreme cold destroys the target tissue	Same
<b>Mode of Use</b>	Cryogen is dispensed into foam applicator which is then applied to the lesion	Cryogen is dispensed into foam applicator which is then applied to the lesion	Same
<b>Storage and Safety Conditions</b>	<ul style="list-style-type: none"> <li>-Keep away from fire or flame</li> <li>-Do not smoke while using the product</li> <li>-Do not puncture or incinerate canister</li> <li>-Do not expose to heat or store at temperatures above 122°F.</li> <li>-Store at room temperature away from heat</li> </ul>	<ul style="list-style-type: none"> <li>-Keep away from fire or flame</li> <li>-Do not smoke while using the product</li> <li>-Do not puncture or incinerate canister</li> <li>-Do not expose to heat or store at temperatures above 122°F.</li> <li>-Store at room temperature away from heat</li> </ul>	Same

**8.1. Comparison Table vs Additional Predicates**

<b>Characteristic</b>	<b>Subject Device:</b> CryoFreeze Wart and Skin Tag Remover	<b>Predicate Device:</b> Skin Clinic Nitro Clear Wart Remover	<b>Predicate Device:</b> Oystershell Pixie Skin Tag Remover	<b>Comparison</b>
Trade Name / Device Name	CryoFreeze Wart and Skin Tag Remover	Skin Clinic Nitro Clear Wart Remover	Oystershell Pixie Skin Tag Remover	Same
510(k) Number	K253000	K242932	K240226	n/a
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	The Skin Clinic Nitro Clear Wart Remover is intended for the OTC treatment of common warts and plantar warts in adults and children 4 years of age and older.	Pixie Skin Tag is a cryogenic device for home use intended to treat skin tags in persons over the age of 21.	<b>Different</b>

	adults age 22 years or older.			
Mechanism of Action	Extreme cold destroys the target tissue	Extreme cold destroys the target tissue	Extreme cold destroys the target tissue	Same

**9. Non-Clinical Performance Data**

Performance testing has demonstrated that the CryoFreeze Wart and Skin Tag Remover cryosurgical device meets the same performance specifications as the predicate device, including output temperature, freeze charge hold time, and visual confirmation of ice ball formation. The modification to the cryogen formulation does not alter the device's intended use, operating principle, or overall safety and effectiveness.

**10. 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 devices.