April 15, 2025

CryoConcepts LP
Sam Niedbala
CEO
1100 Conroy Place
Easton, Pennsylvania 18040

Re: K242932
Trade/Device Name: Skin Clinic NitroClear & Private Label Versions
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: March 16, 2025
Received: March 19, 2025

Dear Sam Niedbala:

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: 2025.04.15 22:50:02 -04'00'

For
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)*
K242932

Device Name
Skin Clinic Nitro Clear Wart Remover

Indications for Use *(Describe)*
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.

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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"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) SUMMARY

(As Required by 21 CFR 807.92)

I. SUBMITTER

CryoConcepts LP
1100 Conroy Place
Easton, PA 18040
Phone: **(215) 853-6276**
Contact: Sam Niedbala, Ph.D.
April 14, 2025

II. DEVICE

Name of Device: **Skin Clinic Nitro Clear Wart Remover**

Usual Name – Cryosurgical unit and accessories

Classification Name – General & Plastic Surgery

Regulatory Class: II

Code of Federal Regulation: 878.4350

Product Code: GEH

III. PREDICATE DEVICES – Class II

Skin Clinic Freeze n' Clear for Skin Tags & Warts K211099

Compound W Nitro-Freeze Wart Remover K172373

IV. DEVICE DESCRIPTION

The **Skin Clinic Nitro Clear Wart Remover** device utilizes extreme cold to facilitate the removal of common and plantar warts by freezing. Each device contains a container of cryogen gas in a plastic holder along with instructions for use. The **Skin Clinic Nitro Clear Wart Remover** device is for OTC use and utilizes Nitrous Oxide cryogen delivered from the cartridge into a tip which acts as a reservoir for the cryogen gas. The applicator tip is cooled to as low as -89°C. Depending on the location and size, the applicator is placed against the common wart or

plantar wart between 10-40 seconds which freezes the targeted area. The frozen wart falls away over time and new epidermis grows in its place. One to four treatments with intervals of two weeks may be required.

V. INDICATIONS FOR USE

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.

VI.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics for the **Skin Clinic Nitro Clear Wart Remover** vs Freeze 'n Clear Skin Clinic for Warts/Skin Tags and the Compound W Nitro-Freeze are provided in the following table. Each of these products utilize similar technological characteristics as shown in the table below.

Technological Characteristics	**Freeze 'n Clear Skin Clinic for Warts and Skin Tags** **(K211099)**	**Compound W Nitro-Freeze Wart Remover** **(K172373)**	**Skin Clinic Nitro Clear Wart Remover** **(Subject Device)**
-Intended Use	The Freeze 'n Clear Skin Clinic for Warts and Skin Tags product is intended for the OTC treatment of common warts, plantar warts, and skin tags. Warts: For use with children 4 years of age and older	For the over-the-counter treatment of common warts and plantar warts. For use with Adults and children 4 years and older	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.
-Cryogen	Mixture of Dimethyl Ether, Propane and Butane	Nitrous Oxide	Nitrous Oxide

Technological Characteristics	Freeze 'n Clear Skin Clinic for Warts and Skin Tags (K211099)	Compound W Nitro-Freeze Wart Remover (K172373)	Skin Clinic Nitro Clear Wart Remover (Subject Device)
-Materials	-canister containing cryogen -Foam Applicators	-Plastic device holding canister of nitrous oxide cryogen -Foam Tip Applicator	- Plastic device holding canister of nitrous oxide cryogen -Plastic Tip Applicator
-Mode of Use	Cryogen dispensed into foam applicator which is then applied to wart	Table-top device with disposable foam applicators	Cryogen dispensed into reusable applicator tip and applied to the target wart
-**Mechanism of action**	Extreme cold destroys the target tissue	Extreme cold destroys the target tissue	Extreme cold destroys the target tissue
-**Storage & 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	-The device is under high pressure and cannot be opened. -Protect from sunlight and do not expose to temperature above 50°C(120°F) before first use or 35°C(95°F) after first use -Store at room temperature away from heat -Keep away from flames or materials that burn easily, or are sources of sparks or ignition, including mobile phones, radios, and other electrical appliances. -Do not smoke or use near and open flame.	-The device is under high pressure and cannot be opened. -Protect from sunlight and do not expose to temperature above 50°C(120°F) before first use or 35°C(95°F) after first use -Store at room temperature away from heat -Keep away from flames or materials that burn easily, or are sources of sparks or ignition, including mobile phones, radios, and other electrical appliances. -Do not smoke or use near and open flame.

Technological Characteristics	Freeze 'n Clear Skin Clinic for Warts and Skin Tags (K211099)	Compound W Nitro-Freeze Wart Remover (K172373)	Skin Clinic Nitro Clear Wart Remover (Subject Device)
		-Do not inhale nitrous oxide	-Do not inhale nitrous oxide
-Treatment Procedure	Spray the cryogen into the applicator and then place it directly onto the wart for a specified number of seconds	Following Device Activation, dispense the cryogen into the applicator and then place it directly onto the wart for a specified number of seconds	Following Device Activation, dispense the cryogen into the applicator and then place it directly onto the wart for a specified number of seconds
Shelf Life	3 Years	3 Years	4 Years
-Disposal	Entire unit is disposable after emptied of cryogen.	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	OTC for consumer use
-Service / Repair	None	None	None

VII. PERFORMANCE DATA

As part of the submission, the product was tested for biocompatibility according to FDA's biocompatibility 2020 guidance and meets the requirements of ISO 10993.

Bench-testing compared the temperatures attained by the Compound W Nitro-Freeze and Freeze n Clear Skin Clinic predicate devices to the Skin Clinic Nitro Clear Wart Remover product to demonstrate that they were comparable. The subject device bench testing showed that equivalent or lower temperatures could be attained using the device. An in vitro test was also performed demonstrating that the subject device and predicate devices were able to kill cells embedded in an agar matrix over the time course of a standard treatment time.

A human factors usability study was performed in support of the over-the-counter indication for the Skin Clinic Nitro Clear Wart Remover product to treat common and plantar warts.

VIII. CONCLUSIONS

The Skin Clinic Nitro Clear Wart Remover product is substantially equivalent to the Freeze n Clear Skin Clinic Wart/Skin Tag product (K211099) and the Compound W Nitro-Freeze wart treatment product (K172373) predicate devices. All devices are intended for OTC treatment of common warts and plantar warts. The combination of studies and performance data presented demonstrates the subject device is as safe and effective as compared to the predicate device(s) for the OTC treatment of common warts and plantar warts by consumers and for use with adults and children 4 years of age and older.