October 25, 2024

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

Re: K242625
Trade/Device Name: Skin Clinic Freeze Point
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: August 30, 2024
Received: September 3, 2024

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.25 09:30:41 -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)*
K242625

Device Name
Skin Clinic Freeze Point

Indications for Use *(Describe)*
The Skin Clinic Freeze Point product is intended for the treatment of common and plantar warts by OTC consumers. May be used with children 4 years of age or older under adult supervision.

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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Premarket Notification

510(K) SUMMARY

(As Required by 21 CFR 807.92)

I. SUBMITTER

CryoConcepts LP,
1100 Conroy Place
Easton, PA 18040
Phone: 855-355-2796
Contact: Sam Niedbala, Ph.D.
October 24, 2024

II. DEVICE

Name of Device: Skin Clinic Freeze Point

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

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

Wartie Wart Remover K140314

IV. DEVICE DESCRIPTION

The Skin Clinic Freeze Point device utilizes extreme cold to facilitate the removal of warts and by freezing. Each kit contains a container of cryogen gas in a plastic holder and instructions for use. The device is for OTC use and utilizes difluoroethane cryogen delivered from the canister into a foam wrapped tip which acts as a reservoir for the cryogen gas. The gas rapidly

evaporates and cools the applicator to as low as -50°C. The applicator is then placed against the wart for up to 40 seconds which freezes the targeted tissue. 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 Freeze Point for Warts product is intended for the OTC treatment of common warts and plantar warts. May be used with children 4 years of age or older under adult supervision.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics for the Skin Clinic Freeze Point for Warts vs Freeze 'n Clear Skin Clinic for Warts/Skin Tags and the Wartie are provided in the following table. Each of these products utilize the same technological characteristics as shown in the table below.

Technological Characteristics	**Freeze 'n Clear Skin Clinic for Warts (K211099)**	**Wartie (K2130314)**	**Skin Clinic Freeze Point for Warts (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.	Wartie Wart Remover is intended for the over the counter treatment of common and plantar warts to be used in adults and children 4 years of age and older	The Skin Clinic Freeze Point for Warts product is intended for the OTC treatment of common warts and plantar warts. May be used with children 4 years of age or older under adult supervision.
-Cryogen	Mixture of DMEP	Mixture of DMEP	Difluoroethane

Technological Characteristics	Freeze 'n Clear Skin Clinic for Warts (K211099)	Wartie (K2130314)	Skin Clinic Freeze Point for Warts (Subject Device)
-Materials	-canister containing cryogen -Foam Applicators	-canister containing cryogen -Metal Tip Applicator	-canister containing cryogen -Foam and Metal Tip Applicator
-Mode of Use	Cryogen dispensed into foam applicator which is then applied to wart	Cryogen dispensed onto metal tip which is then applied to wart	Cryogen dispensed onto foam surrounding the metal tip which is then applied to 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	-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
-Treatment Procedure	Spray the cryogen into the applicator and then place it directly onto the wart for a specified number of seconds	Spray the cryogen into the applicator and then place it directly onto the wart for a specified number of seconds	Spray the cryogen into the applicator and then place it directly onto the wart for a specified number of seconds

Technological Characteristics	Freeze 'n Clear Skin Clinic for Warts (K211099)	Wartie (K2130314)	Skin Clinic Freeze Point for Warts (Subject Device)
-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 including cytotoxicity, sensitivity, irritation according to FDA's biocompatibility 2020 guidance and meets the requirements of ISO 10993.

Bench testing compared the temperatures attained by the Wartie and Freeze n Clear Skin Clinic predicate devices to the Skin Clinic Freeze Point product to demonstrate that they were comparable. Additional bench testing using an in vitro method compared all the same products and showed they were comparable in their ability to freeze and destroy target cells.

A human factors usability study was performed in support of the over-the-counter indication for Skin Clinic Freeze Point product to treat common and plantar warts. The human factors usability testing evaluated consumers ability to comprehend and understand the labelling and use of the product.

VIII. CONCLUSIONS

The Skin Clinic Freeze Point product is substantially equivalent to the Freeze n Clear Skin Clinic Wart/Skin Tag product (K211099) and the Wartie wart treatment product (K140314) predicate devices. All are intended for OTC treatment of common and plantar warts. The combination of studies and performance data presented demonstrates the subject device is as safe and effective as the predicate device(s) for the intended use.