June 17, 2022

CryoConcepts LP
Sam Niedbala PhD
CEO
205 Webster St
Bethlehem, Pennsylvania 18015

Re: K211099
Trade/Device Name: Freeze'n Clear Skin Clinic Warts & Tags
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: April 7, 2021
Received: May 16, 2021

Dear Sam Niedbala PhD:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211099

Device Name

Freeze 'n Clear Skin Clinic for Warts and Skin Tags

Indications for Use *(Describe)*

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.

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.

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K211099 510(K) SUMMARY

I. SUBMITTER

CryoConcepts LP,
205 Webster St,
Bethlehem PA 18015
Phone: 855-355-2796
Contact: Sam Niedbala, Ph.D.
June 16, 2022

II. DEVICE

Name of Device: Freeze 'n Clear Skin Clinic for Warts and Skin Tags

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

OTC Wart Removal System K023487

Histofreezer Professional K933327

Claritag K190747

IV. DEVICE DESCRIPTION

The Freeze 'n Clear Skin Clinic for Warts and Skin Tags product utilizes extreme cold to facilitate the removal of warts and skin tags by freezing. Each kit contains a container of cryogen gas, foam applicators, tweezers and instructions for use. The device is for OTC use and utilizes a combination of dimethyl ether, propane and isobutane delivered from the canister into a

foam applicator which acts as a reservoir for the cryogen gas. The gas rapidly evaporates and cools the applicator to approximately -55°C. The applicator is then placed against the wart or skin tag for 40 seconds which freezes the targeted tissue. The frozen skin tag or 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 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics for the Freeze ’n Clear Skin Clinic for Warts vs Freeze ’n Clear Skin Clinic for Warts and Skin Tags as well as the Histofreezer professional and Claritag predicates are provided in the following table. Each of these products utilize the same technological characteristics and cryogens as shown in the table below.

Technological Characteristics	**Freeze ’n Clear Skin Clinic for Warts (K023487)**	**Histofreezer Professional (K933327)**	**Claritag (K190747)**	**Freeze ’n Clear Skin Clinic for Warts and Skin Tags (Subject Device)**
-Intended Use	The Freeze ‘n Clear Skin Clinic Advanced Wart product is intended for consumer use for the removal of common warts and plantar warts	For the cryosurgical treatment of lesions including warts and skin tags. Rx Only.	Claritag is indicated for use in the treatment of acrochordons (skin tags)	The Freeze ‘n Clear Skin Clinic for Warts and Skin Tags product is intended for consumer use for the treatment of common warts, plantar warts and skin tags
-Cryogen	Mixture of DMEP	Mixture of DMEP	Mixture of DMEP	Mixture of DMEP

Technological Characteristics	Freeze 'n Clear Skin Clinic for Warts (K023487)	Histofreezer Professional (K933327)	Claritag (K190747)	Freeze 'n Clear Skin Clinic for Warts and Skin Tags (Subject Device)
-Materials	-canister containing cryogen -Foam tipped applicators	-canister containing cryogen -Foam tipped applicators	-canister containing cryogen and disposable foam pads, Tweezers	-canister containing cryogen -Foam tipped applicators and -Tweezers
-**Mode of Use**	Cryogen dispensed into foam applicator which is then applied to the lesion	Cryogen dispensed into foam applicator which is then applied to the lesion	Cryogen dispensed into foam pads which are then applied to the lesion	Cryogen dispensed into foam applicator which is then applied to the lesion
-**Mechanism of action**	Extreme cold destroys the target tissue	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	-Highly Flammable -Store at room temperature between 68°-77°F and away from heat. -Protect from sunlight and do not expose to temperature above 120°F -Contents under pressure. -Do not puncture or incinerate	-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

Technological Characteristics	Freeze 'n Clear Skin Clinic for Warts (K023487)	Histofreezer Professional (K933327)	Claritag (K190747)	Freeze 'n Clear Skin Clinic for Warts and Skin Tags (Subject Device)
			container, even if empty	
-Treatment Procedure	Spray the cryogen into the applicator to saturate it and then place it directly onto the lesion for a specified number of seconds	Spray the cryogen into the applicator to saturate it and then place it directly onto the lesion for a specified number of seconds	Spray the cryogen into the foam pads to saturate them and then place them directly onto the lesion for a specified number of seconds	Spray the cryogen into the applicator to saturate it and then place it directly onto the lesion for a specified number of seconds
-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.	Entire unit is disposable after emptied of cryogen.
-Defined Operators	OTC for consumer use	Rx Use Only	Rx Use Only	OTC for consumer use
-Service / Repair	None	None	None	None

VII. PERFORMANCE DATA

This submission added the indication to the Freeze 'n Clear Skin Clinic product to treat skin tags. As part of the data provided, 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 Histofreezer Professional predicate device and Freeze 'n Clear Skin Clinic product to demonstrate that they were equivalent. Additional bench testing using an in vitro model also demonstrated the Histofreezer Professional and Freeze 'n Clear Skin Clinic products were equivalent in their ability to freeze and destroy target cells.

A clinical study and human factors usability study was performed in support of the over-the-counter indication for skin tags. The clinical study was performed at 3 US, dermatology offices with over 300 subjects. It consisted of two parts, a label comprehension part for self-diagnosis and self-selection and an actual use part. Human factors usability testing also evaluated label

comprehension and simulated use. The studies demonstrated the majority of subjects were able to self-diagnosis, self-select for the product, understand the directions, and appropriately use the product. Additionally, historical data was presented showing the low number of complaints and adverse events seen outside the US with the Freeze ‘n Clear product used either for warts or skin tags

VIII. CONCLUSIONS

The Freeze ‘n Clear Skin Clinic K023487 predicate device is indicated for OTC treatment of common and plantar warts. This submission adds the indication for the treatment of skin tags to the Freeze ‘n Clear Skin Clinic K211099 device. The combination of studies and performance data presented demonstrates the subject device is as safe and effective as the predicate device(s) as indicated for use.