June 10, 2024

CryoConcepts LP
Sam Niedbala
Chief Executive Officer
1100 Conroy Place
Easton, Pennsylvania 18040

Re: K240106
Trade/Device Name: Histofreezer V
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 10, 2024
Received: May 10, 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.

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: 2024.06.10 11:18:27 -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.

Submission Number *(if known)*

K240106

Device Name

Histofreezer V (N/A)

Indications for Use *(Describe)*

The Histofreezer V indications for use as follows:
I,1,1,2-tetrafluoroethane, pentafluoroethane, and I,1,1-tri fluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratoses, actinic keratosis, achrochorodon, molluscum contagiosum, age spots, dermatofibroma, small keltoids, granuloma annulare, Porokeratosis Plantaris, Angiomas, Keratoacanthoma, chrondrodermatitis, epithelial nevus, Leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

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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PREMARKET NOTIFICATION 510(K) SUMMARY

I. SUBMITTER

CryoConcepts LP,
1100 Conroy Place
Easton, PA 18040
Phone: 855-355-2796
Contact: Dr. Sam Niedbala
Prepared 29 December 2023

II. DEVICE

Name of Device: Histofreezer V

Usual Name – Cryosurgical unit and accessories
Classification Name – General & Plastic Surgery
Regulatory Class: GEH
Product Code: GEH

III. PREDICATE DEVICES

K130995: CryoDose (Private Label McKesson Brand)

IV. DEVICE DESCRIPTION

The Histofreezer V device utilizes extreme cold to facilitate the removal of benign topical lesions. The device utilizes a combination of 1,1,1,2-Tetrafluoroethane, Pentafluoroethane, and 1,1,1-Trifluoroethane delivered from the cannister of gas into a foam bud or cone which acts as a reservoir for the cryogen gas. To perform the treatment the bud or cone facilitates freezing the targeted lesion for up to 40 seconds.. The frozen lesion 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 Histofreezer V indications for use are as follows:
1,1,1,2-tetrafluoroethane, pentafluoroethane, and 1,1,1-tri fluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratoses, actinic keratosis, achrochorodon, molluscum contagiosum, age spots, dermatofibroma, small keltoids, granuloma annulare, Porokeratosis Plantaris, Angiomas, Keratoacanthoma, chrondrodermatitis, epithelial nevus, Leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

Characteristics	Histofreezer V Subject Device	CryoDose McKesson Private Label K130995
Intended Use	Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane is to be used for the treatment of: • verruca (warts), including plantar and common warts, • seborrheic keratoses, actinic keratoses, Facial and non-Facial • achrochordon (skin tags), • molluscum contagiosum, • age spots, • dermatofibroma • small keloids, • granuloma annulare, • porokeratosis plantaris, • angiomas, • lentigo maligna, • keratoacanthoma • basal cell carcinoma, • bowen's disease, • lentigo discrete, • chondrodermatitis, • epithelial nevus, • leukoplakia, • granuloma pyogenicum, • kaposi's sarcoma • pyogenic granuloma	Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane is to be used for the treatment of: • verruca (warts), including plantar and common warts, • seborrheic keratoses, actinic keratoses, Facial and non-Facial • achrochordon (skin tags), • molluscum contagiosum, • age spots, • dermatofibroma, • small keloids, • granuloma annulare, • porokeratosis plantaris, • angiomas, • lentigo maligna, • keratoacanthoma, • basal cell carcinoma, • bowen's disease, • lentigo discrete, • chondrodermatitis, • epithelial nevus, • leukoplakia, • granuloma pyogenicum, • kaposi's sarcoma • pyogenic granuloma
Cryogen	Mixture of Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane	Mixture of Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane
Cryogen Gas Boiling Point	-48(°C)	-48(°C)
Cone Materials	• Plastic cones of various sizes • Sizes Include: 3, 5, 7, 9,12, 16mm	• Plastic cones of various sizes Sizes Include: 3, 5, 7, 9, 12, 16mm
Mode of Use	Dispense cryogen against the inside wall of the cone and let evaporate or dispense onto foam applicator which is applied to the lesion	Dispense cryogen against the inside wall of the cone and let evaporate or dispense onto foam applicator which is applied to the lesion
Mechanism of action	Cryogen is delivered to the skin by dispensing into the cone or foam applicator	Cryogen is delivered to the skin by dispensing into the cone or foam applicator

Characteristics	Histofreezer V Subject Device	CryoDose McKesson Private Label K130995
Safety	Non-Flammable	Non-Flammable
Operation	Gas dispense initiated by applying pressure to the actuator and stopped by taking pressure off actuator.	Gas dispense initiated by applying pressure to the actuator and stopped by taking pressure off actuator.
Defined Operators	Licensed Medical Professionals (Rx)	Licensed Medical Professionals (Rx)

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

A summary of the technological characteristics for the Histofreezer V versus the predicate devices: McKesson. Each uses the same combination of gases to treat the lesion using an applicator or cone. Each has the same indications for use.

VII. PERFORMANCE DATA

Cryosurgery works to destroy target lesions through applied extreme cold. When sufficient heat has been removed from the treated spot, the tissue is destroyed through cell lysis and vascular stasis.

The Histofreezer V device utilizes a mixture of 1,1,1,2-Tetrafluoroethane, Pentafluoroethane, and 1,1,1-Trifluoroethane delivered from the cannister of gas into a foam bud applicator or cone which acts as a reservoir for the cryogen gas. The predicate CryoDose/McKesson device use this same mixture known as R404A Gas.

Bench testing in this submission focused on demonstrating the equivalency of temperatures over their treatment times while using cone or applicators from the CryoDose/McKesson device and Histofreezer V.

Finally, as part of the data provided, the product was tested for biocompatibility including cytotoxicity, sensitivity, irritation according to FDA's biocompatibility guidance and meets the requirements of ISO 10993.

VIII. CONCLUSIONS

Various types and mixtures of refrigerants are well-established and used in cryosurgical products to achieve sufficiently low temperatures to effect tissue destruction through extreme cold temperatures. The comparison bench testing of the CryoDose/McKesson device compared to the Histofreezer V shows that the temperatures attained are sufficient for cryosurgery. The data, the labelling and bench data supplied supports the substantial equivalence between Histofreezer V and the predicate devices.