March 21, 2018

Bovie Medical Corp.
% Sam Niedbala
CEO
CryoConcepts LP
205 Webster Street
Bethlehem, Pennsylvania 18015

Re: K180211
Trade/Device Name: Freezpoint
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 13, 2018
Received: January 25, 2018

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 (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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180211

Device Name
Freezpoint

Indications for Use *(Describe)*

The Freezpoint device is intended for the surgical destruction of tissue of target tissue by applying cryogenic gases at extreme low temperatures.

The List below shows examples of the types of lesions that may be treated:
- Molluscum Contagiosum
- Skin Tags
- Actinic Keratosis
- Lentigo
- Verruca Plana
- Verruca Vulgaris
- Verruca Plantaris
- Genital Lesions
- Seborrheic Keratosis

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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# 510(k) Summary

## I. SUBMITTER

Bovie Medical Corp.
5115 Ulmerton Road
Clearwater, Florida 33760
Prepared January 08, 2018

Send Correspondence To:
Sam Niedbala, Ph.D.
Phone: 855-355-2796
sam@cryoconcepts.com

## II. DEVICE

Name of Device: Freezpoint
Usual Name – Cryosurgical unit and accessories
Classification Name –General & Plastic Surgery (21CFR 878.4350)
Regulatory Class: II
Product Code: GEH

## III. PREDICATE DEVICE

CryOmega-K102006

## IV. DEVICE DESCRIPTION

The Freezpoint device is designed to dispense a continuous stream of liquid nitrous oxide when actuated. The device uses an 8g or 16g cartridge of nitrous oxide. Licensed Practitioners can then dispense the gas for use in procedures requiring the destruction of tissue using the extreme cold of nitrous oxide, $N_2O$ (-89$^{o}$C).

## V. INDICATIONS FOR USE

The Freezpoint is intended for the surgical destruction of tissue of target tissue by applying cryogenic gases at extreme low temperatures.

The List below shows examples of the types of lesions that may be treated:

- Molluscum Contagiosum
- Skin Tags
- Actinic Keratosis
- Lentigo
- Verruca Plana
- Verruca Vulgaris
- Verruca Plantaris

- Genital Lesions
- Seborrheic Keratosis

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics for the Freezpoint versus the CryOmega predicate is provided in the following table.

| **Technological Characteristics** | **Freezpoint** | **Predicate CryOmega-K102006** |
|---|---|---|
| **-Intended Use Statement** | Intended Use: The Freezepoint is a disposable device with a spray applicator intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures | Intended Use: The CryOmega is a disposable device with a spray applicator intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures |
| **-Cryogen Characteristics** | Nitrous Oxide, $N_2O$ at 50 bar pressure. 16g cartridge | Nitrous Oxide, $N_2O$ at 50 bar pressure. 16g cartridge |
| **-Materials** | Housing: Plastic<br>Filter: Plastic<br>O-rings: Butadiene-rubber<br>Gas Cartridge: Metal | Housing: Plastic<br>Filter: Plastic<br>O-rings: Butadiene-rubber<br>Gas Cartridge: Metal |
| **-Mode of Use** | Apply Spray Topically | Apply Spray Topically |
| -**Mechanism of action** | $N_2O$ gas is delivered to the treatment site at -89C to effect cellular destruction | $N_2O$ gas is delivered to the treatment site at -89C to effect cellular destruction |
| **-Storage Conditions** | <50°C | <50°C |
| **-Safety** | Complies with ASTM: F882-84 (96) for Cryosurgical Medical Instruments | Complies with ASTM: F882-84 (96) for Cryosurgical Medical Instruments |

| | | |
|---|---|---|
| **-Gas Cartridge Safety** | Unit is discarded after cartridge gas is emptied. | Unit is discarded after cartridge gas is emptied. |
| **-Treatment Procedure** | Freezing of target tissue by open spray | Freezing of target tissue by open spray |
| **-Operation** | Gas dispense control using actuator lever. Spray controlled by on/off actuator | Gas dispense control using actuator lever. Spray controlled by on/off actuator |
| **-Disposal** | Whole Unit is disposable after gas is emptied from the cartridge. | Whole Unit is disposable after gas is emptied from the cartridge. |
| **-Defined Operators** | Licensed Practitioner | Licensed Practitioner |
| **-Service/Repair** | Dispose of once gas cartridge is emptied. No Servicing | Dispose of once gas cartridge is emptied. No Servicing |

VII. PERFORMANCE DATA

The following bench testing data was provided in support of the substantial equivalence determination.

The Freezpoint and predicate CryOmega devices both utilize liquid nitrous oxide. Bench testing therefore focused on demonstrating the equivalency of gas dispensed per unit of time and the temperature attained.

Replicate sprays of each device were performed, weighing the devices before and after a 5 second spray. The amount dispensed for the Freezpoint and CryOmega were calculated and found to be <0.01g different. The difference in amount dispensed was therefore negligible. Additionally replicate measurements of gas sprayed onto a thermocouple from each device were all less than -89ºC substantiating the low boiling point of the dispensed liquid nitrous oxide for its intended use.

VIII. CONCLUSIONS

Nitrous oxide is well established as a gas used in cryosurgical products. The comparison bench testing shown between the Freezpoint and CryOmega show that the temperatures attained and amount dispensed are substantially the same. The data therefore supports the substantial equivalence between the Freezpoint and the predicate.