May 25, 2022

CryoScience North America, Inc.
℅ Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, PA 19103

Re: K203661
Trade/Device Name: CRYO Penguin
Regulatory Class: Unclassified
Product Code: MLY
Dated: April 25, 2022
Received: April 25, 2022

Dear Kelliann Payne:

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,

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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 on last page

510(k) Number *(if known)*

K203661

Device Name

CRYO Penguin

Indications for Use *(Describe)*

The CRYO Penguin is indicated for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).

Type of Use *(Select one or both, as applicable)*

X 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

CRYO PENGUIN

1. Submission Sponsor

CRYO-Science North America Inc.
615 Front Street, Suite 103
Whitehall, PA 18052

Mr. Oktawian Pabian
President
Tel: +1-484-763-8596
operations@cryosc.com

2. Submission Correspondent

Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300

Tel: +1-267-675-4687
Fax: +1-267-675-4601
kelliann.payne@hoganlovells.com

3. Date Prepared

May 25, 2022

4. Device Identification

Trade or Proprietary Name:	CRYO Penguin
Common or Usual Name:	Vapocoolant Device
Regulation Number:	N/A
Product Code:	MLY
Class:	Unclassified
Panel:	Physical Medicine

5. Legally Marketed Predicate Device(s)

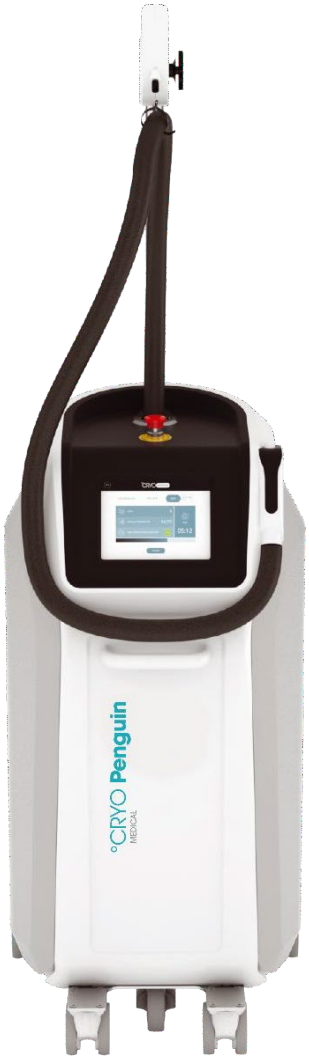
Primary predicate device:
Device Name: CRYOTRON 2® Cryotherapy Device
510(k) number: K030281
Manufacturer: CRYONIC MEDICAL NORTH AMERICA

Secondary predicate device:
Device name: FROZEN N
510(k) number: K193665
Manufacturer: B.M. Tech Worldwide Co., Ltd (formerly Yozma BMTech Co. Ltd.)

6. Indication for Use Statement

The CRYO Penguin is indicated for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).

7. Device Description – CRYO Penguin



CRYO Penguin

The CRYO Penguin utilizes liquid nitrogen (LN2) to provide supercooled air for localized treatment. There are three main components to the device:

- Liquid nitrogen vessel with an evaporator
- Cryogenic hose with a treatment handle
- Electrical box and HMI panel with control software

The CRYO Penguin directs cold gas to the treatment area via a cryogenic hose tipped with a treatment handle. The handle is equipped with a red laser and LED lights to accurately position the treatment handle to provide a readout of the patient's skin temperature.

The treatment handle does not physically touch the patient. To assure that the wand maintains the proper distance to the patient (approximately 15cm), there are two small lasers which provide two laser dots. When these dots converge to one dot, the handle is properly distanced. If the

handle moves closer to the patient or further away, the dots no longer converge, providing a visual cue to the operator that the handle position has changed and is no longer optimal.

Additionally, a temperature sensor and LED lights monitor optimal skin surface temperature; LED lights indicate skin temperature status as follows:

- GREEN - the skin temperature is too high for optimum treatment (above 4°C) and should be further cooled.
- BLUE - the skin temperature is at the desired temperature (in the range of 2-4°C).
- RED - the skin temperature is too low (below 2°C), and the treatment handle is removed or moved further away from the patient. If the temperature of the skin surface is below -1°C for 1 second, auto-off function activates.

The CRYO Penguin is software driven via pre-programmed protocol. Treatment time is monitored via countdown timer which is adjustable based on the treatment desired. Note: The protocol is selected prior to the session and may not be changed during the session.

The CRYO Penguin may only be operated by a trained and authorized person.

8. Substantial Equivalence Discussion

The following table compares the CRYO Penguin to the selected predicate devices 'CRYOTRON 2® Cryotherapy Device' and 'FROZEN N' with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness compared to the predicate devices.

Comparison of Technological Characteristics

Attribute	CRYO Penguin (Subject Device)	CRYOTRON 2® Cryotherapy Device (Primary Predicate Device)	FROZEN N (Secondary Predicate Device)	Comparison
510(k) Number	K203661	K030281	K193665	n/a
Product Code	MLY	MLY	GEH, MLY	Same as the primary predicate device (CRYOTRON 2®)
Regulation Number	None	None	878.4350	Same as the primary predicate device (CRYOTRON 2®)
Indication for Use	The CRYO Penguin is indicated for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).	The CRYOTRON 2® Cryotherapy Device is indicated for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).	The 'Frozen N' cryotherapy device using liquid nitrogen vapor, is for use when cold therapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures, minor sprains or other minor sports injuries, and as an adjunct to rehabilitative treatment (e.g., intermittent cold with stretch).	Same

Attribute	CRYO Penguin (Subject Device)	CRYOTRON 2® Cryotherapy Device (Primary Predicate Device)	FROZEN N (Secondary Predicate Device)	Comparison
Mechanism of Action	Liquid nitrogen is used to provide a flow of cold vapor to the patient on the body part where cryotherapy is to be applied. Gas temperatures of -162°C can be delivered.	The patented technology of the CRYOTRON 2® Cryotherapy Device uses the natural expansion of liquid CO_2 to create a cold spray of micro-crystals delivered under pressure. Using a gradual sweeping motion, the user applies the spray to the treatment site for 30-60 seconds at a distance of 3-5 inches. Rapid cooling (thermal shock) occurs when the spray sublimates (passes directly from solid (ice) phase to gas phase) as it contacts the skin.	LN2 gas is delivered to the treatment site at -196°C to effect thermal shock.	All three devices function by delivering a cold gas to cool the intended skin area: evaporation of liquid nitrogen (LN) for the CRYO Penguin and FROZEN N devices, and natural expansion of carbon dioxide for the CRYOTRON 2® Cryotherapy Device.
Coolant	Liquid nitrogen	Compressed medical-grade carbon dioxide	Liquid nitrogen	CRYO Penguin and FROZEN N devices both use liquid nitrogen. CRYOTRON 2® uses compressed carbon dioxide. The difference does not raise new questions of safety and effectiveness.

Attribute	CRYO Penguin (Subject Device)	CRYOTRON 2® Cryotherapy Device (Primary Predicate Device)	FROZEN N (Secondary Predicate Device)	Comparison
Product Design	Cylindrical grip handpiece, electronic console for controlling the operation. LCD display. Laser for proper positioning mounted on the handpiece. Temperature is monitored via IR temperature sensor.	The CRYOTRON 2® Cryotherapy Device consists of four components that are housed in a mobile cart: • A pistol-grip hand-piece that delivers the carbon dioxide spray. • An electronic console/control panel that provides operational information to the user. • A rechargeable battery. • A cylinder of compressed medical-grade carbon dioxide gas (sold separately).	Cylindrical grip handpiece, electronic console for controlling operation (7" LCD screen). LN2 gas cylinder (included) and Laser pointer mounted on the hand-piece beside nozzle. Temperature is monitored via IR temperature sensor.	Essentially identical. Each device displays current treatment parameters during the cryotherapy treatment.
Nozzle Temperatures	Temperature can reach Maximum of -196°C to-162°C.	Not publicly available.	Temperature can reach -196°C	The temperature achieved by CYRO Penguin is similar to FROZEN N, which also uses cold nitrogen vapors. Because the maximum temperature of expanded carbon dioxide is about -78°C, the temperature of sprayed carbon dioxide would be higher. However, because the targeted skin-temperatures are similar among these three devices, difference in the nozzle

Attribute	CRYO Penguin (Subject Device)	CRYOTRON 2® Cryotherapy Device (Primary Predicate Device)	FROZEN N (Secondary Predicate Device)	Comparison
				temperatures does not raise new questions of safety and effectiveness.
Treatment duration	30-60 seconds	30-60 seconds	30-60 seconds	Same
Target skin temperature	2-4℃	Not publicly available	2-4℃	Similar
Distance between skin and the nozzle	15 cm (about 6 inches)	3-5 inches	12 cm (about 5 inches)	The distance between skin and the nozzle is similar for each device.
Auto-off	-1℃	Not publicly available	-1℃	Auto-off function for CRYO Penguin and FROZEN N devices are the same.

Attribute	CRYO Penguin (Subject Device)	CRYOTRON 2® Cryotherapy Device (Primary Predicate Device)	FROZEN N (Secondary Predicate Device)	Comparison
Mobility	Housed in a mobile cart	Housed in a mobile cart	Housed in a mobile cart	Same
Electrical Safety Testing Passed	IEC 60601-1	Not publicly available	IEC 60601-1	Same for CRYO Penguin and FROZEN N device

Non-Clinical Performance Data

To demonstrate the safety and effectiveness of the CRYO Penguin device and to show substantial equivalence to the predicate devices, CryoScience completed the following non-clinical tests. Results confirm that the design and performance specifications for the device are met. The CRYO Penguin passed test requirements as identified below:

- *Electrical Safety and essential performance testing*
  Testing was conducted in accordance with IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- *Electromagnetic Compatibility*
  Testing was conducted in accordance with IEC 60601-1-2:2014. Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests. There was no potential deviation.

- *Software*
  Software validation report contains Software verification and validation testing as recommended in IEC 62304:2006 Medical device software -- Software life cycle processes and FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005).

- *Verification Testing*
  The skin temperature test on three anatomical locations in three human subjects verified that the temperature of a treatment area on skin dropped to 2 - 4°C within 30 seconds as intended and maintained for additional 30 seconds. Temperature sensor and monitoring testing verified that LED lights correctly indicate skin temperature status as follows: 1) Green color if skin temperature above 4ºC; 2) BLUE color if skin temperature is between 2ºC and 4ºC or 3) RED color if skin temperature below 2ºC.

9. Clinical Performance Data

No clinical data is included with this submission.

10. Statement of Substantial Equivalence

The CRYO Penguin devices have identical intended use as the CRYOTRON 2® and FROZEN N devices and similar technological characteristics (delivery of cryogenic temperature gas to affected tissues). Minor differences in technological characteristics do not raise new or different questions of safety or efficacy. Performance testing has demonstrated the CRYO Penguin is as safe and effective as the predicate devices. Therefore, the CRYO Penguin device is substantially equivalent to the predicate devices.