May 28, 2020

YOZMA BMTECH CO., LTD.
% Dave Kim
President, MTech Group
7707 Fannin St. Ste 200
Houston, Texas 77054

Re: K193665
Trade/Device Name: Frozen N
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 1, 2019
Received: April 3, 2020

Dear Dave Kim:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193665

Device Name

FROZEN N

Indications for Use *(Describe)*

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).

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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510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510(k) summary prepared: May 26, 2020

I. SUBMITTER

Owner:	YOZMA BMTECH CO., LTD. #609, #808, #1001~1007, Jungang lnduspia 5-cha, 137, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea (13202) Tel.: +82 (31) 7395544
Contact person	Jenny Cho (jennycho@yozma-bmtech.com) / RA Team Manager
Official Correspondent	Dave Kim (davekim@mtech-inc.net) 7707 Fannin St. Ste 200, Houston, TX 77054 Tel.: +713-467-2607

II. DEVICE

Trade/proprietary Name	FROZEN N
Classification Name	Unit, Cryosurgical, Accessories
Common/Usual Name	Cryotherapy Device
Regulation & product code	21 CFR 878.4350 (GEH, MLY)
Regulatory Class	Class II
510(k) Review Panel	General & Plastic Surgery

III. PREDICATE DEVICE

Trade/proprietary Name	FROZEN C
Manufacturer	B.M.Tech Worldwide Co., Ltd. (old name of YOZMA BMTECH. CO., LTD)
510(k) Number	K182392
Regulation & product code	21 CFR 878.4350 (GEH, MLY)

Prescription Use only.
Predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The FROZEN N is a local cryotherapy device used for cooling down tissues by means of nitrogen vapors. Liquid nitrogen, whose boiling point is -196°C, inside the vessel changes into the gas form by heating from a rod-shaped immersion heater operated by AC power. The appearing difference in pressure between atmospheric pressure and the vessel provokes the flow of nitrogen vapors from the vessel to the hose finished with a nozzle mounted on handpiece. The nozzle discharge volume of nitrogen vapors is controlled in 5 levels by the operation time of heater. As the amount of nitrogen decreases, the device is off automatically when the temperature of the heater reaches 60°C where sensed via bimetallic thermometer embedded in heater module. The structural design of device is the movable cart equipped with a weighing system to check the amount of nitrogen in the vessel. Rapid cooling (thermal shock) in the temperature range of 2~4 °C occurs within 30-45 seconds when the spray sublimates as it contacts the skin.

The device is controlled via touch screen keys of LCD where displays the timer, measured temperature, operating level and remains of nitrogen. Also, the touch key controls the aiming beams mounted on the nozzle side of handpiece that helps the user keeping a proper distance while the two laser beams meet each other. The LED on the hand-piece flickers when the measured drops below 5°C and the device automatically shuts down when the measured temperature stays -1 °C or below for 1 second.

V. INDICATIONS FOR USE

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).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same or equivalent technical characteristics as the predicate device including materials, design, and energy source. There are no technological differences between the predicate and the submitted device. Refer to the following table for the comparison between the subject device and the predicate:

	FROZEN N K193665	**FROZEN C** K182392
Indication for use and Intended use	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).	The FROZEN hyperbaric CO2 cryotherapy device, 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).

Product design		Cylindrical grip hand-piece, electronic console for controlling operation (7" LCD screen), LN2 gas cylinder (included) and laser pointer mounted on the hand-piece beside nozzle	Cylindrical grip hand-piece, electronic console for controlling operation (7" LCD screen), CO2 gas cylinder (sold separately) and laser pointer mounted on the hand-piece beside nozzle
Energy delivered		Thermal energy via refrigerant spray	Thermal energy via refrigerant spray
Cryogen		Medical-grade Liquid Nitrogen gas (Sold separately)	Medical-grade carbon dioxide gas (Sold separately)
Mechanism of action		LN2 gas is delivered to the treatment site at -196℃ to effect thermal shock	CO2 gas is delivered to the treatment site at -78.5℃ to effect thermal shock
Firmware		Ver 1.1.0 (FROZENN)	Ver 1.0.0 (FROZENC)
Mobility		Housed in a mobile cart	Housed in a mobile cart
Patient contact		None	None
Working principle	**Treatment time per procedure**	30-60 seconds	30-60 seconds
	Distance of topical spray	12 cm (about 5 inches)	7 cm (about 3 inches)
	Treatment temperature	2-4℃ in 30-45 seconds	2-4℃ in 30-45 seconds
	Measurement	Skin temperature by infrared temperature sensor	Skin temperature by infrared temperature sensor
	Auto-off	-1℃	-1℃

Substantial Equivalence

The cryotherapy devices including both of subject and predicate devices use cryogenic liquids, vapor and cold gases to local cooling of the body surface. The subject device FROZEN N is substantially equivalent in design, manufacturing material, intended use, working principle, and technical characteristics to the FROZEN C cryotherapy device (K182392) and raise no new issues of safety or effectiveness.

For the mechanism of action, the predicate device (K182392) does not include the cylinder to be filled with compressed carbon dioxide in liquid state but provide the connector conforming to CGA320, which is the US Carbon Dioxide Cylinder Valve outlet standard. Instead, the subject device uses an unpressurised liquid nitrogen but that is venting at a boiling point of -196℃, thus providing an insulated container designed to withstand rapid temperature changes.

While the design differences of gas discharge method between subject device and predicate, the intended use (indication for use) is identical for cryotherapy which does not require cell destruction by freezing. The difference of cryogenic boiling points between CO2 and LN2 medical grade gases does not raise any new questions of safety and effectiveness since the clinical effect is led from the local cooling of the body surface where its skin temperature of affected area is exposed to 2-4°C in 30-60 seconds. The safety and performance of subject device has been properly validated throughout the electrical safety testing, EMC testing and bench testing.

VII. PERFORMANCE DATA

Similar performance tests established in the predicate (K182392) submission was performed to demonstrate the Substantial Equivalence, including but not limited to the skin temperature test on human subjects to verify the device can generate the needed temperature range (2-4 ℃) for cold therapy safely and effectively. Performance bench testing including temperature accuracy and time to arrive intended temperature have been tested. The difference of the temperature on LCD and the actual skin surface was within the tolerance level, ±2℃.

The temperature of a treatment area on skin dropped to 2 ~ 4℃ within 30s as intended. The FROZEN N complies with voluntary standards for electrical safety and EMC testing. The following data were provided to support the substantial equivalence determination:

Electrical Safety and essential performance testing was conducted in accordance with

- AAMI ANSI ES 60601-1:2005/(R) 2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

Electromagnetic Compatibility:

Testing was conducted in accordance with IEC 60601-1-2:2014 (Ed.4) 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).

Summary of clinical tests

Clinical testing was not required to demonstrate the substantial equivalence of the FROZEN N to its predicate device

VIII. CONCLUSIONS

Based on the label and technology comparison as well as the performance testing, the subject device FROZEN N is substantially equivalent to the predicate device listed above.