October 30, 2018

% Mr. Dave Kim
MTech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K182392
Trade/Device Name: Frozen C
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH, MLY
Dated: August 24, 2018
Received: September 4, 2018

Dear Mr. 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
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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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
Indications for Use

510(k) Number *(if known)*
K182392

Device Name
FROZEN C

Indications for Use *(Describe)*
The FROZEN C, 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).

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

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

Date 510(k) summary prepared: October 24, 2018

I. SUBMITTER

Owner: B.M.Tech Worldwide Co., Ltd.
#609, #808, #1001-1007, Jungang Induspia 5-cha, 137, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea (13202)
Tel.: +82 (31) 7395544

Contact person Jenny Cho (jennycho@bmtech21.com) / RA Team Manager

Official Correspondent Dave Kim (davekim@bmtech-inc.net)
8310 Buffalo Speedway, Houston, TX 77025
Tel.: +713-467-2607

II. DEVICE

Trade/proprietary Name FROZEN C
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 CRYOFOS & Accessories
Manufacturer CRYOFOS Medical GmbH
510(k) Number K170810
Regulation & product code 21 CFR 878.4350 (GEH, MLY)
Regulatory Class Class II
510(k) Review Panel General & Plastic Surgery

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

The FROZEN C Cryotherapy Device uses a compressed medical-grade liquid carbon dioxide as cryogen to deliver a topical refrigerant. Using the natural expansion of liquid CO2, it creates a cold spray of microcrystals delivered under pressure. The FROZEN C Cryotherapy Device consists of a cylindrical grip hand-piece, touchscreen console for operation and display, infrared temperature sensor, and a cylinder of compressed medical-grade carbon dioxide gas (sold separately). The touchscreen provides continuous monitoring by displaying the measured skin temperature, treatment duration by timer set, and residual volume of CO2 gas. The user applies the CO2 spray to the treatment site for 30-60 seconds at a distance of 7cm through a gradual circular motion of hand-piece. Rapid cooling (thermal shock) occurs when the spray sublimates (passes directly from solid (ice) phase to gas phase) as it contacts the skin.

The contact point where the two laser pointers meet is designed to guide the appropriate distance from the skin surface where the skin temperature is measured. If the laser pointer is not required by use environment, it is easy to deactivate by using on/off button in the touch screen. The LED on the hand-piece flickers when the measured temperature drops below 5°C and the device automatically shut down when the measured temperature stays below 0°C for 1 seconds.

V. INDICATIONS FOR USE

The FROZEN C, 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).

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 C | CRYOFOS & Accessories  
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Subject device</td>
<td>(K170810)</td>
</tr>
<tr>
<td>Indication for use and</td>
<td>The FROZEN C, hyperbaric</td>
<td>The CRYOFOS and Accessories</td>
</tr>
<tr>
<td>Intended use</td>
<td>CO2 cryotherapy device, is for</td>
<td>indicated for use when cold</td>
</tr>
<tr>
<td></td>
<td>use when cold therapy is</td>
<td>therapy is indicated for the</td>
</tr>
<tr>
<td></td>
<td>indicated for the temporary</td>
<td>temporary reduction of pain,</td>
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<td></td>
<td>reduction of pain, swelling,</td>
<td>swelling, inflammation, and</td>
</tr>
<tr>
<td></td>
<td>inflammation, and hematoma</td>
<td>hematoma from minor surgical</td>
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<tr>
<td></td>
<td>from minor surgical procedures,</td>
<td>procedures, minor sprains or</td>
</tr>
<tr>
<td></td>
<td>minor sprains or other minor</td>
<td>other minor sports injuries, and</td>
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<td></td>
<td>sports injuries, and as an adjunct</td>
<td>as an adjunct to rehabilitative</td>
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<tr>
<td></td>
<td>to rehabilitative treatment (e.g.,</td>
<td>treatment (e.g., intermittent cold</td>
</tr>
<tr>
<td></td>
<td>intermittent cold with stretch).</td>
<td>with stretch).</td>
</tr>
</tbody>
</table>

2/4
<table>
<thead>
<tr>
<th><strong>Product design</strong></th>
<th>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</th>
<th>Pistol-grip hand-piece, electronic console for controlling operation, rechargeable battery, CO2 gas cylinder (sold separately) and</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mobility</strong></td>
<td>Housed in a mobile cart</td>
<td>Housed in a mobile cart</td>
</tr>
<tr>
<td><strong>Patient contact</strong></td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td><strong>Energy delivered</strong></td>
<td>Thermal energy via refrigerant spray</td>
<td>Thermal energy via refrigerant spray</td>
</tr>
<tr>
<td><strong>Cryogen</strong></td>
<td>Compressed medical-grade carbon dioxide gas (Sold separately)</td>
<td>Compressed medical-grade carbon dioxide gas (Sold separately)</td>
</tr>
<tr>
<td><strong>Mechanism of action</strong></td>
<td>CO2 gas is delivered to the treatment site at -78.5°C to effect thermal shock</td>
<td>CO2 gas is delivered to the treatment site at -78.5°C to effect thermal shock</td>
</tr>
<tr>
<td><strong>Working principle</strong></td>
<td><strong>Treatment duration</strong></td>
<td><strong>Treatment duration</strong></td>
</tr>
<tr>
<td></td>
<td>30-60 seconds</td>
<td>30-60 seconds</td>
</tr>
<tr>
<td><strong>Distance of topical spray</strong></td>
<td>7 cm</td>
<td>7 cm</td>
</tr>
<tr>
<td><strong>Treatment temperature</strong></td>
<td>2-4°C</td>
<td>2-4°C</td>
</tr>
<tr>
<td><strong>Measurement</strong></td>
<td>Skin temperature by infrared temperature sensor</td>
<td>Skin temperature by infrared temperature sensor</td>
</tr>
</tbody>
</table>

**Substantial Equivalence**

The predicate device is a legally marketed device. The subject device has the same intended use (Indications for Use) as the predicate device. There is demonstrated equivalency in basic product design and fundamental technology, indication for use, mechanism of action and working principle. The subject device and the predicate device have the same structural composition with minor differences. They all are consist 3 basic product components of hand-piece to deliver the CO2 spray, electronic console to control the operation and the compressed medical-grade CO2 gas cylinder (sold separately). The measured skin temperature is continuously displayed on the console (LCD) during treatment, same as the predicate device, but the colored indication on LCD screen is provided along with beep sound and the blue LED on hand-piece flashes when the skin surface temperature falls below 5°C. To improve protection function from the cold stress, coolant spray automatically shut down if the measured temperature drops below 0°C for 1 seconds.

There are two differences between the predicate and subject devices. One of the differences is change of handpiece appearance from pistol grip to cylindrical grip. And the other difference is that our products do not use batteries, unlike comparison devices. However, these differences do not significantly affect safety and/or effectiveness.
VII. PERFORMANCE DATA

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°C.

The temperature of a treatment area on skin dropped to 2~4°C within 30s as intended. The FROZEN C 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*

*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:*

*Summary of clinical tests*
Clinical testing was not required to demonstrate the substantial equivalence of the FROZEN C to its predicate device

VIII. CONCLUSIONS

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