



March 31, 2022

RecensMedical, Inc.
% Dave Kim, MBA
President
Mtech Group
7505 Fannin Street, Suite 610
Houston, Texas 77054

Re: K220674
Trade/Device Name: TargetCool
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH, MLY
Dated: February 11, 2022
Received: March 8, 2022

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

Indications for Use

510(k) Number (if known)

K220674

Device Name

TargetCool™

Indications for Use (Describe)

TargetCool™ 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.

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510(k) SUMMARY**K220674****1. ADMINISTRATIVE INFORMATION**

Manufacturer Name	RecensMedical, Inc. 908, SK V1 center, 830 Dongtansunhwan-daero, Hwaseong-si, Gyeonggi-do, Republic of Korea
Phone:	+82 31 8043 3064
Fax:	+82 31 630 2092
Contact person:	Yeonui Lee / Regulatory Affairs Manager yui.lee@recensmedical.com
Office Correspondent:	Dave Kim, MBA Mtech Group 7505 Fannin St. Ste 610, Houston, TX 77054 +1-713-467-2607 davekim@mtech-inc.net

2. DEVICE NAME AND CLASSIFICATION

Trade name:	TargetCool™
Common name :	Cryosurgical Device
Classification name:	Cryosurgical Unit and Accessories
Classification Regulations:	21 CFR 878.4350 / 21 CFR 878.4810
Class:	Class II
Classification Panel:	General & Plastic Surgery
Product code:	GEH, MLY

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3. PRIMARY PREDICATE DEVICE

510(k) Number:	K203481
Trade name:	CryoVIVE
Classification name:	Cryosurgical Unit and Accessories
Classification Regulations:	21 CFR 878.4350
Class:	Class II
Classification Panel:	General & Plastic Surgery
Product code:	GEH, MLY

4. INDICATIONS FOR USE

TargetCool™ 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).

5. DEVICE DESCRIPTION

TargetCool™ is a handheld device that can deliver rapid, precise, and controlled cooling to the skin tissue. The TargetCool™ device consists of a main device Cooling-Nozzle, a guard, a filter, and a cartridge.

In Cooling mode, the main device produces controlled cooling based on thermoelectric cooling, which controls the temperature (2-4°C) of the targeted area. TargetCool™ displays the skin temperature measured in real time, the set cooling temperature and time, and the device status through the LCD display. Also, if the measured temperature is below -1°C and lasts for more than 1 second, the status light blinks in blue with a beep sound.

The principle of pain relief through skin cooling is as follows: As the skin cools by spraying the cryogen onto the skin, the nerve conduction velocity (NCV) of the skin decreases, increasing the pain threshold (PTH) and pain tolerance (PT). Through this mechanism, pain in the skin is relieved. The advances represented by TargetCool™ lie in the fact that the device executes this process in a precise, controlled, and rapid way.

6. PERFORMANCE DATA

The Company's Performance Data for TargetCool™ is as follows:

Bench Testing

TargetCool™ complies with all applicable standards, including ISO 13485:2016, IEC 60601-1 for electrical safety and IEC 60601-1-2 for electromagnetic compatibility.

Biocompatibility (ISO 10993) was also performed to demonstrate conformance with established industry standards. The only patient-contacting material on TargetCool is the guard, which is comprised of polycarbonate. The polycarbonate is the exact same material used in CryoVIVE, which was FDA-cleared under K203481. Therefore, the biocompatibility test is not applicable for the TargetCool™. The device hazard analysis was completed and risk-control implemented to mitigate identified hazards.

TargetCool Temperature accuracy tests were conducted targeting three different treatment areas (wrist, arm, back of neck) by three physicians at three different temperature settings (-10, -5, 5 degree C).

It was confirmed that the skin surface temperature reached 2~4°C within 5 seconds, also it was maintained at 2 to 4 °C for the maximum spraying time (60 seconds).

The testing results support that all the specifications have met the acceptance criteria of each module and interaction of processes.

TargetCool™ passed all testing and supports the claims of substantial equivalence and safe operation.

7. TECHNOLOGY COMPARISON and SUBSTANTIAL EQUIVALENCE Discussion

Product Name	TargetCool™ (K220674)	CryoVIVE (K203481)	Comparison
Indications for Use / Intended Use	TargetCool™ 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).	<p>The CryoVIVE (Freezing mode) is indicated for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures</p> <ul style="list-style-type: none"> - Molluscum Contagiosum - Skin Tags - Actinic Keratosis - Lentigo - Verruca Plana - Verruca Vulgaris - Verruca Lesions - Genital Lesions - Seborrheic Keratosis <p>CryoVIVE (Cooling mode) 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).</p>	Same (Cooling mode)
Component	Main system, Trigger, LCD Display, Cooling-Nozzle, Guard tip, Filter, Cartridge	Main system, Control button, LCD, Nozzle (Cooling and Freezing), Guide tip, filter, CO ₂ cartridge	Similar

Mechanism of Action	The unit blows very low-temperature gas at temperature and time settings, onto the desired treatment area	(Cooling mode) The unit blows very low-temperature gas at temperature and time settings, onto the desired treatment area (Freezing mode) Cryogen, CO ₂ is delivered to the treatment site to affect cellular destruction	Same (Cooling mode)
Cryogen Type	CO ₂	CO ₂	Same
Temperature	Reaching 2-4 °C within 5 sec	(Cooling mode) Reaching 2-4 °C within 5 sec (Freezing mode) -79°C	Same (Cooling mode)
Treatment Duration	0~60 sec	0~60 sec	Same
Gas Volume	65g cartridge	60g cartridge	Similar
Safety feature	Alarm and status light blinking if the temperature of the skin is determined to be less than -1 °C for 1 second.	Alarm and status light blinking if the temperature of the skin is less than -1 °C for 1 second.	Same

Compared with the predicate device, the subject device has the following modifications: 1). the freezing mode is removed; 2). the subject device can be driven by the internal battery, but not external AC Mains; 3). when the target temperature is reached, the status light and beep sound activate; 4) when continuous spraying is used, a beep sound occurs at set time intervals.

However, these differences do not significantly affect safety and/or effectiveness. Therefore, TargetCool™ is substantially equivalent to the predicate device.

8. CONCLUSION

TargetCool™ is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and performance temperature to CryoVIVE (K203481) for cooling mode operation. Performance testing data established that TargetCool™ is as safe and effective as the legally marketed predicate device for the proposed indications. On this basis and in accordance with 21 CFR§ 807.100(b), TargetCool is substantially equivalent to the predicate device.