July 22, 2022

RecensMedical Inc.
Yeonui Lee
Regulatory Affairs Manager
908, SK V1 center, 830 Dongtansunhwan-daero
Hwaseong-si, Gyeonggi-do 18468
Korea, South

Re: K221234
Trade/Device Name: TargetCool
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 26, 2022
Received: May 26, 2022

Dear Yeonui Lee:

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,

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221234

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.

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

K221234

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
Date of the summary preparation	May 23, 2022
Contact person:	Yeonui Lee / Regulatory Affairs Manager yui.lee@recensmedical.com
Office Correspondent:	Dave Kim, MBA Mtech Group 7707 Fannin St. Ste 200, 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 ll
Classification Panel:	General & Plastic Surgery
Product code:	GEH, MLY

3. PRIMARY PREDICATE DEVICE

510(k) Number:	K220674
Trade name:	TargetCool
Classification name:	Cryosurgical Unit and Accessories
Classification Regulations:	21 CFR 878.4350
Class:	Class ll
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. 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.

Clinical Testing

Clinical publications and clinical data demonstrated the safety and effectiveness of the TargetCool™ for treatment of pediatric patient.

7. SUBSTANTIAL EQUIVALENCE

The comparison chart below provides evidence to support the equivalence determination between TargetCool™ and the predicate device (K220674) with respect to intended use, technological characteristics and principles of operation. TargetCool™ shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate device.

Product Name	TargetCool™ (Subject Device)	TargetCool (K220674)	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).	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).	Same
Component	Main system, Trigger, LCD Display, Cooling-Nozzle, Guard, Filter, Cartridge	Main system, Trigger, LCD Display, Cooling-Nozzle, Guard, Filter, Cartridge	Same
Mechanism of Action	The unit blows very low-temperature gas at temperature and time settings, onto the desired treatment area	The unit blows very low-temperature gas at temperature and time settings, onto the desired treatment area	Same
Cryogen Type	CO_2	CO_2	Same
Temperature	Reaching 2-4 °C within 5 sec	Reaching 2-4 °C within 5 sec	Same
Treatment Duration	0~60 sec	0~60 sec	Same
Gas Volume	65g cartridge	65g cartridge	Same
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

TargetCool™ is the same as the device cleared in K220674. No changes have been made to the device to change the contraindication. TargetCool™, the subject device, is equivalent to the predicate device.

8. CONCLUSION

TargetCool™ and the legally marketed predicate devices have the same intended use, Indications for Use statement and the technological characteristics. While the contraindication differs between the two systems. Clinical literatures and clinical data demonstrate that TargetCool™ is as safe and effective as the legally marketed predicate devices and that TargetCool™ does not raise any different questions of safety or effectiveness than the predicate. On this basis and in accordance with 21 CFR§ 807.100(b), TargetCool™ is substantially equivalent to the predicate device.