



June 22, 2023

RecensMedical, Inc.
Lee Yeonui
Regulatory Affairs Manager
#507, #908, SK V1 center, 830 Dongtansunhwan-daero
Hwaseong-si, Gyeonggi-do 18468
Korea, South

Re: K230599
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: May 26, 2023
Received: May 26, 2023

Dear Lee Yeonui:

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,

Mark

Trumbore -S

Digitally signed by Mark
Trumbore -S

Date: 2023.06.22
11:57:21 -04'00'

Mark Trumbore

Assistant Director, THT4A1: Robotically-Assisted Surgical
Devices Team

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)
K230599

Device Name
TargetCool™

Indications for Use (Describe)

TargetCool™ (Cooling mode / Boosting 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).

TargetCool™ (Freezing mode) is indicated for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures

- Molluscum Contagiosum
- Skin Tags
- Actinic Keratosis
- Lentigo
- Verruca Plana
- Verruca Vulgaris
- Verruca Lesions
- Genital Lesions
- Seborrhic Keratosis

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

1. ADMINISTRATIVE INFORMATION

Manufacturer Name	RecensMedical, Inc. #507, #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	March 01, 2023
Contact person:	Yeonui Lee / Regulatory Affairs Manager yui.lee@recensmedical.com

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

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. SECOND PRIDICATE DEVICE

510(k) Number:	K221234
Trade name:	TargetCool™
Classification name:	Cryosurgical Unit and Accessories

Classification Regulations:	21 CFR 878.4350
Class:	Class II
Classification Panel:	General & Plastic Surgery
Product code:	GEH, MLY

5. INDICATIONS FOR USE

TargetCool™ (Cooling mode, Boosting) 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™ (Freezing mode) is indicated for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures

- Molluscum Contagiosum
- Skin Tags
- Actinic Keratosis
- Lentigo
- Verruca Plana
- Verruca Vulgaris
- Verruca Lesions
- Genital Lesions
- Seborrheic Keratosis

6. 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, nozzle, a guard, a filter, and a cartridge.

The main device produces controlled cooling based on thermoelectric cooling, which controls the temperature 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.

7. 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.

8. 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.

[TargetCool™-Cooling mode, Boosting mode]

Product Name	TargetCool™ (Subject Device)	TargetCool™ (K221234)	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, Control button, LCD, Cooling nozzle, Freezing nozzle, Cooling guard, filter, CO ₂ cartridge and Boosting accessories (Boosting nozzle, a Boosting guard, and a	Main system, Trigger, LCD Display, Cooling-Nozzle, Guard, Filter, CO ₂ Cartridge	Difference

	Boosting Container).		
Mechanism of Action	The unit blows very low-temperature gas and cold-water at temperature and time settings, onto the desired treatment area		Similar
Mode type	Cooling Mode, Boosting Mode		Difference
Cryogen Type	CO ₂ , Cold-water (Saline solution)		Same
Temperature	2-4 °C within 5 sec		Same
Treatment Duration	Cooling Mode	Continuous (0 sec) PL (2 sec pre-set) 1~60sec	0~60 sec
	Boosting Mode	3~4 min	
Gas Volume	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.		Same

The Cooling mode & Boosting mode of TargetCool™ is equivalent in intended use, principles of operation, and performance temperature to TargetCool™ (K221234) and raises no new issues of safety or effectiveness.

The differences are the Boosting mode and the Boosting accessories for the Boosting mode.

In Boosting mode, saline cooled by CO₂ gas is sprayed onto the skin. The saline solution is used for the purpose of keeping the skin temperature constant at 2-4°C for 3-4 minutes and for safety purposes to prevent the skin temperature from dropping below freezing.

Cooling mode uses CO₂ gas and Boosting mode uses cold-water, but the temperature of Cooling mode and Boosting mode is the same (2~4°C). Therefore, the difference does not raise new questions of safety and effectiveness

[TargetCool™-Freezing mode]

Product Name	TargetCool™ (Subject Device)	CryoVIVE (K203481)	Comparison
Indications for Use / Intended Use	TargetCool™ are intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures - Molluscum Contagiosum - Skin Tags - Actinic Keratosis - Lentigo - Verruca Plana - Verruca Vulgaris - Verruca Lesions - Genital Lesions - Seborrheic Keratosis	The CryoVIVE are intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures - Molluscum Contagiosum - Skin Tags - Actinic Keratosis - Lentigo - Verruca Plana - Verruca Vulgaris - Verruca Lesions - Genital Lesions - Seborrheic Keratosis	Same
Component	Main system, Control button, LCD, Cooling nozzle, Freezing nozzle, Cooling guard, filter, CO ₂ cartridge and Boosting accessories (Boosting Nozzle, a Boosting guard, and a	Main system, Control button, LCD, Nozzle (Cooling and Freezing), Guide tip, filter, CO ₂ cartridge	Same

	Boosting Container).		
Mechanism of Action	Cryogen, CO ₂ is delivered to the treatment site to effect cellular destruction	Cryogen, CO ₂ is delivered to the treatment site to effect cellular destruction	Same
Temperature	CO ₂ (-79°C)	CO ₂ (-79°C)	Same
Gas dispensing rate	0.578 g/sec	0.578 g/sec	Same
Gas Volume	65g cartridge	65g cartridge	Same
Tissue damage	Cell necrosis occurs only inside the ice ball	Cell necrosis occurs only inside the ice ball	Same

Cryoablation is the fundamental technological principle for the freezing mode of the subject device, TargetCool™, and the predicate devices (CryoVIVE).

The Freezing mode of TargetCool™ is equivalent in intended use, principles of operation, and performance temperature to TargetCool™ (K221234) and raises no new issues of safety or effectiveness. The only difference is that the freezing nozzle's length is shortened and the guard is not inserted during the procedure in the freezing mode. Because of this the device can be placed closer to the lesion, so that it can be applied to smaller lesion sizes. However, these differences do not significantly affect safety and/or effectiveness.

8. CONCLUSION

TargetCool™ and the legally marketed predicate devices have the same intended use, Indications for Use statement and the technological characteristics. While the technological characteristics differ between the two systems, the differences are minor. Performance testing data established that the TargetCool™ is safe and effective as the legally marked predicate devices and that the TargetCool™ does not raise any different questions of safety and effectiveness than the predicate.

On this basis and in accordance with 21 CFR§ 807.100(b), TargetCool™ is substantially equivalent to the predicate device.