October 16, 2025

RecensMedical Inc.
Yeonui Lee
#507, #908, SK V1 center, 830 Dongtansunhwan-daero
Hwaseong-si, Gyeonggi-do 18468
Republic Of Korea

Re: K253114
Trade/Device Name: TargetCool™ (RM-DT02W)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH, MLY
Dated: September 24, 2025
Received: September 24, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.16 20:56:38 -04'00'

Colin Kejing Chen
Acting 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253114

Please provide the device trade name(s).

TargetCool™

Please provide your Indications for Use below.

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
- Seborrheic Keratosis

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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	September 22, 2025
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 ll
Classification Panel:	General & Plastic Surgery
Product code:	GEH, MLY

3. PRIMARY PREDICATE DEVICE

510(k) Number:	K230599
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™ (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
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- Actinic Keratosis
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- 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.

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. The device hazard analysis was completed and risk-control measures were implemented to mitigate identified hazards. Performance testing confirmed compliance with the addition of the 120g cartridge and the charging display modification. The testing results further support that all specifications met the acceptance criteria of each module and the interactions of processes. TargetCool™ passed all testing and substantiates the claims of substantial equivalence and safe operation.

8. SUBSTANTIAL EQUIVALENCE

The comparison chart below provides evidence to support the equivalence determination between TargetCool™ and the predicate device (K230599) 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™ (K230599)		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, Guard, filter, CO_2 cartridge and Boosting accessories (Boosting Nozzle, a Boosting guard, and a Boosting Container).		Main system, Control button, LCD, Cooling Nozzle, Freezing Nozzle, Guard, filter, CO_2 cartridge and Boosting accessories (Boosting Nozzle, a Boosting guard, and a Boosting Container).		Same
Mechanism of Action	The unit blows very low-temperature gas and cold-water at temperature and time settings, onto the desired treatment area		The unit blows very low-temperature gas and cold-water at temperature and time settings, onto the desired treatment area		Same
Mode type	Cooling Mode, Boosting Mode		Cooling Mode, Boosting Mode		Same
Cryogen Type	CO_2, Cold-water (Saline solution)		CO_2, Cold-water (Saline solution)		Same
Temperature	2-4 °C within 5 sec		2-4 °C within 5 sec		Same
Treatment Duration	Cooling Mode	Continuous (0 sec) PL (2 sec pre-set) 1~60sec	Cooling Mode	Continuous (0 sec) PL (2 sec pre-set) 1~60sec	Difference
	Boosting Mode	3~4 min (65g) 5~6 min (120g)	Boosting Mode	3~4 min	
Gas Volume	65g cartridge 120g cartridge		65g cartridge		Difference
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 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™ (K230599) and raises no new issues of safety or effectiveness.

The difference from the predicate device is the addition of a 120 g CO_2 cartridge. This change increases the volume of CO_2 gas, thereby extending the treatment duration while maintaining the same temperature performance as the original device. Therefore, this difference does not raise new questions regarding safety or effectiveness.

[TargetCool™-Freezing mode]

Product Name	TargetCool™ (Subject Device)	TargetCool™ (K230599)	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	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	Same
Component	Main system, Control button, LCD, Cooling Nozzle, Freezing Nozzle, Guard, filter, CO_2 cartridge and Boosting accessories (Boosting Nozzle, a Boosting guard, and a Boosting Container).	Main system, Control button, LCD, Cooling Nozzle, Freezing Nozzle, Guard, filter, CO_2 cartridge and Boosting accessories (Boosting Nozzle, a Boosting guard, and a Boosting Container).	Same
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 120g cartridge	65g cartridge	Difference
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, and the predicate devices (TargetCool™).

The Freezing mode of TargetCool™ is equivalent in intended use, principles of operation, and performance temperature to TargetCool™ (K230599) and raises no new issues of safety or effectiveness. The difference from the predicate device is the addition of a 120 g CO_2 cartridge. This change increases the volume of CO_2 gas, thereby extending the treatment duration while maintaining the same temperature performance as the original device. Therefore, this difference does not raise new questions regarding safety or effectiveness.

8. CONCLUSION

TargetCool™ and the legally marketed predicate devices have the same intended use, Indications for Use statement and the technological characteristics. 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.