



October 15, 2025

RecensMedical, Inc.
Minju Choi
Regulatory Affairs Manager
#507, #908, SK V1 Center, 830 Dongtansunhwan-daero
Hwaseong-si, Gyeonggi-do 18468
Republic Of Korea

Re: K253348
Trade/Device Name: TargetCool-e
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH, MLY
Dated: September 29, 2025
Received: September 30, 2025

Dear Minju Choi:

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: 2025.10.15 10:19:31
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Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K253348

Device Name

TargetCool-e

Indications for Use (Describe)

TargetCool-e (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-e (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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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
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Date of the summary preparation	September 29, 2025
Contact person:	Minju Choi/ Regulatory Affairs Manager mj.choi@recensmedical.com

2. DEVICE NAME AND CLASSIFICATION

Trade name:	TargetCool-e
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:	K230599
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

4. INDICATIONS FOR USE

TargetCool-e (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-e (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

5. DEVICE DESCRIPTION

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

The main device produces controlled cooling based on thermoelectric cooling, which controls the temperature of the targeted area. TargetCool-e 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.

6. PERFORMANCE DATA

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

Bench Testing

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

TargetCool-e is substantially equivalent to the predicate device, TargetCool (K230599), with the only difference being that the subject device does not require a disposable filter for cartridge installation. TargetCool-e features a built-in puncture pin, and the CO₂ cartridge includes a seal cap on the mounting part, allowing direct attachment without a separate disposable filter. All other components used with TargetCool (K230599)—including the Guard, Cooling Nozzle, Boosting Nozzle, Freezing Nozzle, Boosting Container, and Boosting Guard—are identical for TargetCool-e.

Performance testing was conducted with both the 65 g and 120 g CO₂ cartridges. Testing confirmed that all specifications met the acceptance criteria for each module and the overall device function.

TargetCool-e passed all testing and substantiates substantial equivalence as well as safe and effective operation.

Biocompatibility evaluation was considered in accordance with ISO 10993. The only patient-contacting component of TargetCool-e is the guard, which is made of polycarbonate. This material is identical to that used in the predicate device (K230599). Therefore, additional biocompatibility testing was not required.

The device hazard analysis was completed and risk-control implemented to mitigate identified hazards. The Performance testing results support that all the specifications have met the acceptance criteria of each module and interaction of processes.

7. SUBSTANTIAL EQUIVALENCE

The comparison chart below provides evidence to support the equivalence determination between TargetCool-e and the predicate device (K230599) with respect to intended use, technological characteristics and principles of operation. TargetCool-e shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate device.

[TargetCool-e-Cooling mode, Boosting mode]

Product Name	TargetCool-e (Subject Device)		TargetCool™ (K230599)		Comparison
Indications for Use / Intended Use	TargetCool-e 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, 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).		Difference
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	Same
	Boosting Mode	3~4 min (65g) 5~6 min (120g)	Boosting Mode	3~4 min	Difference

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-e is equivalent in intended use, principles of operation, and performance temperature to TargetCool™ (K230599) and raises no new issues of safety or effectiveness. The subject device differs from the predicate device in the following aspects:

First, the subject device allows cartridges to be attached directly without a filter. The CO₂ cartridge includes a seal cap on the mounting part, which simplifies installation and eliminates the need for a separate filter. Second, a 120 g CO₂ cartridge is available in addition to the existing 65 g option. This larger cartridge increases the volume of CO₂ gas available, thereby extending the treatment duration while maintaining the same temperature performance as the predicate device. These differences do not raise new issues of safety or effectiveness.

[TargetCool-e-Freezing mode]

Product Name	TargetCool-e (Subject Device)	TargetCool™ (K230599)	Comparison
Indications for Use / Intended Use	TargetCool-e 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 TargetCool is 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, 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).	Difference
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,

consistent with the predicate device (TargetCool™). The freezing mode of TargetCool-e is equivalent in intended use, principles of operation, and performance temperature to TargetCool™ (K230599), and raises no new issues of safety or effectiveness.

The subject device incorporates two design differences from the predicate device. First, the subject device allows the CO₂ cartridge to be attached directly without a filter. The cartridge is equipped with a seal cap at the mounting part, simplifying installation and eliminating the need for a separate filter. Second, a 120 g CO₂ cartridge option has been added in addition to the existing 65 g cartridge. This larger cartridge increases the available CO₂ volume, thereby extending the treatment duration while maintaining the same temperature performance as the predicate device.

These modifications do not raise new questions regarding safety or effectiveness.

8. CONCLUSION

TargetCool-e 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-e is safe and effective as the legally marked predicate devices and that the TargetCool-e 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-e is substantially equivalent to the predicate device.