May 13, 2021

Recens Medical Inc.
% Dave Kim
President
Mtech Group
7707 Fannin Street Ste 200-V111
Houston, Texas 77054

Re: K203481
Trade/Device Name: CryoVIVE
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH, MLY
Dated: March 15, 2021
Received: March 15, 2021

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

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)*
K203481

Device Name
CryoVIVE

Indications for Use *(Describe)*

The CryoVIVE(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

The 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).

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

K203481

5/12/2021

1. ADMINISTRATIVE INFORMATION

Manufacturer Name	Recensmedical Inc. 908, SK V1 center, 830 Dongtansunhwan-daero, Hwaseong-si, Gyeonggi-do, Republic of Korea
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2. DEVICE NAME AND CLASSIFICATION

Trade name:	CryoVIVE
Common name :	Cryosurgical Device
Classification name:	Cryosurgical Unit and Accessories
Classification Regulations:	21 CFR 878.4350
Class:	Class ll
Classification Panel:	General & Plastic Surgery
Product code:	GEH, MLY

3. PRIMARY PREDICATE DEVICE

510(k) Number:	K190407
Trade name:	CryoLab
Classification name:	Cryosurgical Unit and Accessories

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

4. SECOND PREDICATE DEVICE

510(k) Number:	K170810
Trade name:	Cryofos
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. REFERENCE DEVICE INFORMATION

510(k) Number:	K172769
Trade name:	CryOmega Flexx
Classification name:	Cryosurgical Unit and Accessories
Classification Regulations:	21 CFR 878.4350
Class:	Class II
Classification Panel:	General & Plastic Surgery
Product code:	GEH

6. INDICATIONS FOR USE

The CryoVIVE(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

The 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).

7. DEVICE DESCRIPTION

The CryoVIVE is a handheld device that delivers rapid, precise and controlled cooling temperature to the skin tissue with the use of CO_2 gas cartridge. The CryoVIVE consists of main system, nozzles(Cooling nozzle and Freezing nozzle), Guide tip, filter, and CO2 cartridge. The CryoVIVE offers two treatment modes, which can be changed by using different nozzles. In cooling mode, the main device produces controlled cooling based on thermoelectric cooling, which control the temperature (2-4°C) of targeted area. In freezing mode, the main device delivers the CO_2 gas of extreme cold temperature (-79°C) ,which causes the surgical destruction of target tissue. The CryoVIVE displays the skin temperature measured in real time, the set cooling temperature and time, and the device status through the LCD screen. Also, if the temperature below -1°C lasts for more than 1 second, the front LED blinks in blue with a beep sound.

8. PERFORMANCE DATA

The Company's Performance Data for the CryoVIVE is as follows:

Bench Testing

The CryoVIVE complies with all applicable standards, including ISO 13485:2003, 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 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.
The CryoVIVE passed all testing and supports the claims of substantial equivalence and safe operation.

Clinical Testing

No performance data has been provided since the CryoVIVE is equivalent to the previously cleared predicate devices with no new issues regarding safety and effectiveness.

9. SUBSTANTIAL EQUIVALENCE

The comparison chart below provides evidence to facilitate the substantial equivalence determination between the CryoVIVE and the predicate devices (K190407, K172769) as well as the reference device (K170810) with respect to intended use, technological characteristics and principles of operation. The CryoVIVE shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to both devices.

CryoVIVE, the subject device, the predicate and the reference devices are all cryosurgical instruments ; these devices can be used to cool tissue or freeze tissue in dermatologic procedures of the skin. Since the CryoVIVE has two operating modes: Cooling mode and Freezing mode, the predicate device and the reference device were selected and compared for freezing mode and cooling mode, respectively.

[CryoVIVE - Freezing mode]

Product Name	CryoVIVE (K203481)	Cryolab (K190407)	CryOmega Flexx (K172769)
Indications for Use / Intended Use	The CryoVIVE(Freezing mode) 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 CryoLab® 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	The CryOmega Flexx is intended for the surgical destruction of tissue of target tissue by applying cryogenic gases at extreme low temperatures. The List below shows examples of the types of lesions that may be treated: • Molluscum Contagiosum • Skin Tags • Actinic Keratosis • Lentigo • Verruca Plana • Verruca Vulgaris • Verruca Plantaris • Genital Lesions • Seborrheic Keratosis
Component	Main system, Control button, LCD, Nozzle(Cooling and Freezing), Guide tip, filter, CO_2 cartridge	Housing, Filter, O-rings, Gas(CO_2 or N_2O) Cylinder	Housing, spray tip applicator, gas cartridge (N_2O) with internal valve
Mechanism of	Cryogen,CO_2 is delivered to	Cryogen, N_2O or CO_2 is	N_2O gas is delivered to

action	the treatment site to effect cellular destruction	delivered to the treatment site to effect cellular destruction	the treatment site at -89°C to effect cellular destruction
Temperature	CO_2 (-79°C)	N_2O (-89°C) , CO_2 (-79°C)	N_2O (-89°C)
Gas Volume	60g cartridge	20 oz cylinders	16g or 25g cartridge
Gas dispensing rate	0.581 g/sec	Unidentified	Unidentified
Tissue damage	Cell necrosis occurs only inside the ice ball (Ice ball size is margin(1~3mm) freeze beyond the lesion)	Cell necrosis occurs only inside the ice ball (Ice ball size is margin(1~3mm) freeze beyond the lesion)	Cell necrosis occurs only inside the ice ball (Ice ball size is margin(1~3mm) freeze beyond the lesion)

Cryoablation is the fundamental technological principle for the freezing mode of the subject device, CryoVIVE, and the predicate devices (Cryolab and CryOmega Flexx). The subject and marketed predicate devices are used to ablate unwanted tissue by application of extreme cold. The technological differences that exist between the subject device and the predicate devices. However, these differences do not significantly affect safety and/or effectiveness.

[CryoVIVE – Cooling mode]

Product Name	CryoVIVE (Subject Device)	CRYOFOS (K170810)	Comparison
Indications for Use / Intended Use	The 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).	The CRYOFOS and Accessories indicated for use when cold therapy 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).	The intended use of both devices are similar.
Component	Main system, Control button, LCD, Nozzle(Cooling and Freezing), Guide tip, filter, CO2 cartridge	Pistol grip handpiece, control console, battery and CO2 gas cylinder	Different (the CryoVIVE is a handheld device using CO2 cartridge while the Cryofos uses a gas cylinder.)
Mechanism of action	The unit blows very low-temperature gas at	The unit blows very low-temperature air onto the	same

	temperature and time settings, onto the desired treatment area	desired treatment area	
Cryogen Type	CO_2	CO_2	same
Temperature	Reaching 2-4 °C within 5 sec	Reaching 2-4 °C within 30 sec	Similar
Treatment duration	0~60 sec	30~60 sec	Similar
Gas dispensing rate	0.148g/sec	Unidentified	
Safety feature	Alarm and LED blinking if the temperature of the skin is -1 °C or less for 1 second.	CRYOFOS shuts down if the temperature of the skin is less than -1 °C for 1 second.	Similar

The Cooling mode of CryoVIVE is substantially equivalent in intended use, principles of operation, and performance temperature to Cryofos (K170810) and raises no new issues of safety or effectiveness. The only difference to the marketed reference is the type of a gas container. The performance benchmark testing confirmed the temperature of 2~4 °C is reached by the subject device while the lowest temperature is -79 °C for the subject device and -78.5 °C for the predicate device. The subject device has a warning alarm when the temperature of the skin is -1 °C or less for 1 second. 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 (PTO)1. Through this mechanism, pain in the skin is relieved.

The type of a gas container does not affect the pain relief application. It does not raise any new questions of safety and effectiveness. It was proved by the performance test that the temperature range at the target skin area was the same as that of the predicate device and the reference device. Therefore, CryoVIVE, the subject device, is equivalent to the predicate device and the reference device.

8. CONCLUSION

The CryoVIVE and the legally marketed predicated devices have the same intended use and Indications for Use statement. While the technological characteristics differ between the two systems, the differences are minor. Performance testing data established that the CryoVIVE is safe and effective as the legally marked predicate devices and that the CryoVIVE 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), the CryoVIVE is substantially equivalent to the predicate device and the reference device.