September 24, 2020

R2 Technologies, Inc.
Ms. Ragan Reppond
Sr. Director, HR & Corporate Affairs
2603 Camino Ramon, Suite 200
San Ramon, California 94583

Re: K201260
Trade/Device Name: Dermal Cooling System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH, MLY
Dated: July 24, 2020
Received: July 27, 2020

Dear Ms. Reppond:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201260

Device Name
Dermal Cooling System

Indications for Use *(Describe)*
The Dermal Cooling System is a cryosurgical instrument intended for use in dermatologic procedures for the removal of benign lesions of the skin and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

The Dermal Cooling System is intended to be used by trained healthcare professionals.

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
K201260

I. SUBMITTER

R2 Technologies, Inc.
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Bishop Ranch 3
San Ramon, CA 94583

Contact: Ms. Ragan Reppond
Sr. Director, HR & Corporate Affairs
R2 Technologies, Inc.
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rreppond@r2technologies.com

Date Prepared: July 24, 2020

II. DEVICE

Name of Device:	Dermal Cooling System
Common or Usual Name:	Cryosurgical unit and accessories
Classification Name:	Cryosurgical unit and accessories (21 CFR 878.4350)
Regulatory Class:	II
Product Code:	GEH, MLY

III. PREDICATE DEVICE

The primary predicate device is the Dermal Cooling System, K171398.
The secondary predicate device is the FROZEN C device, K182392.

IV. DEVICE DESCRIPTION

The Dermal Cooling System is a cryosurgical device used to cool the skin, without the use of cryogenic gases or liquids, for the removal of benign skin lesions and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures. Surface contact cooling is achieved using a thermoelectric cooler (TEC), with an integrated aluminum plate, to lower the temperature of the skin. It is intended for use in a healthcare facility such as a clinic or doctor's office.

The Dermal Cooling System is comprised of the following components:

- control unit – houses user interface display, the system controller, and the power converters
- chiller – provides circulating coolant to the handpiece to remove heat from the TEC
- handpiece – contains the TEC, temperature sensors, the aluminum cooling plate, and user interface elements
- isolation transformer – isolates system from AC mains power
- cart – houses the isolation transformer, chiller, and control unit

The control unit initiates the treatment parameters and receives feedback from temperature sensors in the handpiece during the procedure. The user interface provides the mechanism for selection of the treatment plan, initiation of treatment, and display of treatment status.

The non-sterile, reusable handpiece contains the TEC which cools the aluminum contact plate to the treatment temperature, while the circulation of fluid past the TEC allows for the removal of heat. Thermistors affixed to the aluminum contact plate monitor the temperature at the treatment site.

The Dermal Cooling System has three operational modes: cooling off, pre-cool, and treatment. Cooling off represents the resting state; no power is supplied to the TEC in the handpiece. Pre-cool is the state during which the aluminum contact plate in the handpiece is cooled prior to treatment. Treatment is the normal treatment state in which the contact plate temperature is controlled to a pre-defined temperature defined in the treatment plan, as selected from the user interface on the control unit. The minimum temperature is -30°C and the maximum temperature is 40°C; the maximum treatment duration is 300 seconds.

The user interface is the means by which the user can view system status and state of each operational mode. The software provides three primary functions: allowing the user to select a treatment plan; establishing communications with the TEC controller and chiller; and monitoring and displaying treatment progress.

Use of a TEC with closed-loop temperature feedback for cooling, as provided by the Dermal Cooling System, allows the selected temperature to be precisely and accurately maintained throughout the treatment. The TEC controller in the control unit communicates to the TEC module in the handpiece, maintaining the temperature defined in the treatment plan selected by the user. As heat is removed from the skin through contact with the aluminum plate, it is then transferred through the TEC module to the heat exchanger, which is fluid cooled. The chiller maintains a continuous flow of coolant which is circulated through the heat exchanger to carry heat way from the TEC module. The Dermal Cooling System generates sufficient thermal power to cool the aluminum contact plate to a pre-set temperature over a pre-set time. The temperature of the cooling surface, as measured by the thermistor affixed to the aluminum contact plate, is fed into the TEC controller which modulates power to the TEC such that the surface temperatures are precisely controlled. The Dermal Cooling System has an automatic shut-off feature if the temperature for the TEC and cooling plate are out of range.

The Dermal Cooling System operates from standard 120 VAC (60 Hz) power to provide controlled, active cooling at the skin interface throughout the procedure.

V. INDICATIONS FOR USE

The Dermal Cooling System is a cryosurgical instrument intended for use in dermatologic procedures for the removal of benign lesions of the skin and for use when cooling is intended for the temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

The Dermal Cooling System is intended to be used by trained healthcare professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Dermal Cooling System ("subject device") and the predicate devices are cryosurgical instruments that deliver extreme cold temperatures for cooling of the skin.

The primary predicate, the Dermal Cooling System, has not been modified for the proposed expanded indication, i.e., temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures.

The secondary predicate, the FROZEN C, is included to substantiate the proposed expanded indications for use as the currently cleared indication for the FROZEN C (K182392) includes "temporary reduction of pain, swelling, inflammation, and hematoma from minor surgical procedures". The Dermal Cooling System and the FROZEN C have these same fundamental scientific technological elements:

- cooling devices, classified under 21 CRF 878.4350, product code GEH, that have the ability to deliver extreme cold;
- comprised of a cooling unit with a handpiece used to cool the skin in the area intended for treatment;
- software control of the treatment parameters, display of the treatment information, and monitoring of the temperature at the skin during treatment;
- capability to provide the treatment conditions at the skin surface for the proposed indication.

The key difference that exists between the Dermal Cooling System and the FROZEN C is:

- use of a chilled aluminum plate at the treatment site (cooled by a thermoelectric cooler, TEC).

This difference in cooling delivery, the use of a chilled contact plate versus a refrigerant spray, does not raise new questions of safety and effectiveness with respect to the proposed expanded indication.

VII. PERFORMANCE DATA

Performance data were provided in support of the substantial equivalence determination, as summarized in the table on the following page.

Bench testing was completed to demonstrate the ability of the Dermal Cooling System to meet performance specifications (e.g., cooling characteristics when subjected to varied contours and body geometries).

Test	Test method/Requirement	Acceptance criteria	Results
System Validation	System performance when subjected to varied contours and body geometries	System is able to cool skin's surface to between +2°C and +4°C and maintain temperature for 10 minutes	Passed
		Handpiece does not stick to tissue and no visible blanching	Passed

No other performance testing was performed for the subject device for this Traditional 510(k) since there was no change to the device design or methods for use required for the proposed expanded indication

and the range of treatment parameters previously cleared for the Dermal Cooling System (K171398) allows the same cooling characteristics at the skin surface as the secondary predicate, FROZEN 2 device.

No preclinical or clinical testing was performed.

VIII. CONCLUSIONS

The Dermal Cooling System that is the subject of this Traditional 510(k) is substantially equivalent to both the primary predicate (Dermal Cooling System) and the secondary predicate (FROZEN C). The subject device and both predicates are Class II devices intended for use to apply extreme cold to cool tissue. The subject Dermal Cooling System and the primary predicate Dermal Cooling System are the same device; there was no change required in the device design or methods for use for this expanded indication. The Dermal Cooling System can deliver the same treatment parameters to the skin surface and provides similar safety features as the secondary predicate FROZEN C device. The difference in the method by which the skin is cooled to the desired temperature between the subject device (contact cooling) and the secondary predicate (spray cooling) does not raise new questions of safety and efficacy for the proposed expanded indication.