DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 7, 2017

R2 Dermatology, Inc.
Mr. Bijesh Chandran
Sr. Director, RA/QA
2633 Camino Ramon, Suite 130
San Ramon, California 94583

Re: K171398
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
Dated: May 10, 2017
Received: May 12, 2017

Dear Mr. Chandran:

This letter corrects our substantially equivalent letter of July 6, 2017.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171398

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.

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
K171398

I. SUBMITTER

R2 Dermatology, Inc.
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San Ramon, CA 94583

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Date Prepared: July 2, 2017

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

III. PREDICATE DEVICE

The predicate device is the R2 Dermal Cooling System, K161480.

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. 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 in which the aluminum contact plate on the handpiece is cooled prior to treatment. Treatment is the normal treatment state in which temperature is controlled to a pre-defined treatment plan, as selected from the user interface on the control unit. The minimum cooling temperature is -30°C and the maximum warming temperature is 40°C; the maximum treatment duration is 300 seconds.
The user interface is the means by which the system implements each of the operational modes. The software provides three primary functions: setting up the display by which the user can select a treatment plan; establishing communications with the TEC controller to monitor and control temperature; and monitoring treatment progress.

Use of a TEC for cooling at the treatment site, as provided by the Dermal Cooling System, allows the selected temperature to be maintained throughout the duration of treatment. The TEC controller in the control unit communicates to the TEC module in the handpiece, maintaining the treatment plan selected by the user. As the skin is cooled through contact with the aluminum plate, heat is removed. The heat is then transferred from the aluminum plate to the TEC module in the handpiece. The chiller maintains a continuous flow of coolant 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 controller such that the surface temperatures can be precisely controlled.

The Dermal Cooling System operates off 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.

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified Dermal Cooling System and the predicate have these same fundamental scientific technological elements:

- freezing tissue without the use of cryogenic liquids or gases;
- contact surface cooling at a targeted treatment site on the skin;
- use of a thermoelectric cooler (TEC) to cool the aluminum contact surface; and
- software control of the treatment parameters and display of the treatment information.

The key differences between the modified device and the predicate are:

- Updates to user interface and selection of treatment parameters
- Relocation of user interface features to handpiece
- Additional features to convey information on treatment progress
- Display of applied pressure at skin interface
- Increased cooling power
- Integration of system components into single portable entity
- Increase in maximum temperature to 40°C

The modifications do not raise new questions of safety or efficacy for the intended use of cooling at the skin interface for the removal of benign lesions. The intended use and indications for use have not changed; the scientific technological elements have not changed. The modifications to the system were implemented to improve usability of the device, e.g., to reduce the steps required by the user for set up of the system and treatment, and to make it more commercially appealing.

VII. PERFORMANCE DATA

Performance data were provided in support of the substantial equivalence determination, as summarized in the table on the following page. These tests included design verification, electrical safety, usability, and subsurface temperature measurements.

Bench testing was completed to demonstrate the ability of the Dermal Cooling System to meet device and performance specifications (e.g., component accuracy, cooling characteristics).

Usability testing was performed by individuals with varying degrees of experience using the Dermal Cooling System. Individuals were trained in the use of the device and then asked to perform a mock cooling procedure on a simulated test system. All users successfully completed the mock procedure and demonstrated understanding of the device features thereby validating the improvements made to the user interface for this update.

Substantial equivalence testing was performed to demonstrate that the cryoablation zone created with the modified Dermal Cooling System was equivalent to that of the predicate. An in vitro simulated model was used to allow the recording of subsurface measurements. Measurements documented with the in vitro model verified the creation of a substantially equivalent cryoablation zone.

Test	Test method/Requirement	Acceptance criteria	Results
System Verification	Force sensor accuracy	All measured values must be within specification, and within tolerance of calibrated controls as appropriate (e.g., force and thermistor accuracy)	Passed
	Thermistor accuracy		Passed
	Maintenance of cold plate temperature with worst case simulated heat load		Passed
	Power performance characteristics: o acceptance of power o regulation of input power o reverse polarity protection		Passed
	Weight (i.e., handpiece, system)		Passed
	Handpiece LEDs, beeper, and buzzer activation	LEDs cycle through color/beeper sequence, buzzer activates per specification	Passed
	Maintenance of cold plate temperature for fixed duration at: o minimum temperature (-30°C) o maximum temperature (+40°C)	Temperature maintained within specification for duration of test	Passed
Electrical Safety	System to demonstrate electrical safety, IEC 60601-1	Per standard, based on report from Safety Equipment Laboratory	Passed
	System to demonstrate suitability with respect to electromagnetic interference, IEC 60601-1-2		Passed
	System to demonstrate usability, IEC 60601-1-6		Passed
System Validation	System performance with exposure to operating and storage conditions	System must pass functional performance test (e.g., pre-cool, cooling, warming) after exposure to operating/storage conditions	Passed
	Usability - simulated use (with novice and experienced users) to demonstrate function of modified interface and handpiece features	Users must be able to successfully perform all tasks associated with treatment (e.g., turn system on, select treatment plan, initiate treatment, cancel treatment, etc.)	Passed
	Subsurface temperature test - demonstrate creation of cryoablation zone at depth of 1mm	Measured temperature at 1mm of ≤ -20°C	Passed

Software verification and validation testing was conducted per FDA's "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January 2002). The software for this device was considered as moderate level of concern. All tests were successfully passed by meeting the acceptance criteria.

There were no changes to patient contacting material and, as such, biocompatibility testing was not repeated.

No preclinical or clinical testing was performed.

VIII. CONCLUSIONS

The modified Dermal Cooling System and the predicate (as cleared in K161480) have the same intended use and the same technological characteristics e.g., contact cooling without the use of cryogenic gas or liquid, the use of a TEC to cool the aluminum contact plate, and software control. The performance data demonstrate that the device performs to specification and is expected to be equivalent to the predicate, in safety and effectiveness, for the specified use conditions. The modified Dermal Cooling System is, therefore, determined to be substantially equivalent to the predicate.