DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 5, 2016

R2 Dermatology, Inc.
Kristine Tatsutani, Ph.D.
Chief Scientific Officer
Bishop Ranch 3, 2633 Camino Ramon, Suite 130
San Ramon, California 94583

Re: K161480
Trade/Device Name: R2 Dermal Cooling System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 7, 2016
Received: September, 8, 2016

Dear Dr. Tatsutani:

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 yours,

Jennifer R. Stevenson -A

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)*
K161480

Device Name

R2 Dermal Cooling System

Indications for Use *(Describe)*

The R2 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
K161480
R2 DERMATOLOGY, INC.

I. SUBMITTER **R2 Dermatology, Inc.**
Suite 130
Bishop Ranch 3
2633 Camino Ramon
San Ramon, CA 94583

Contact: Kristine Tatsutani, PhD
Chief Scientific Officer
R2 Dermatology, Inc
Phone: 925-378-4400
Fax: 925-378-4495
ktatsutani@r2derm.com

Date Prepared: October 3, 2016

II. DEVICE

Name of Device:	R2 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 primary predicate device is the CryoPen® Surgical System, K110754.
The secondary predicate device is the Galil Medical Visual-Ice® Cryoablation System, K152133.

IV. DEVICE DESCRIPTION

The R2 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 the user interface, the system controller, and the power source
- handpiece – contains the TEC, thermistors, and the aluminum cooling plate in a thermoplastic housing
- chiller - provides circulating water to the handpiece to remove heat extracted by the TEC
- isolation transformer – isolates system from AC power

The control unit initiates the treatment parameters and receives feedback from thermistors at the skin cooling interface during the procedure. The user interface provides the mechanism for the input of the specific treatment parameters (e.g., temperature, time, number of treatment cycles), initiation of cooling, display of treatment data (e.g. temperature at the aluminum contact plate, remaining treatment time), and selection of treatment options (e.g., active warming, automated treatment parameters).

The non-sterile, reusable handpiece contains the thermoelectric cooler (TEC) which cools the aluminum contact plate to the selected treatment temperature, while the circulation of fluid past the TEC allows for the removal of heat. Thermistors at the aluminum contact plate monitor the temperature during pre-cooling, treatment, and warming.

The Dermal Cooling System has four operational modes: cooler off, pre-cool, treatment, and warming. Cooler off represents the resting state; the chiller is on but no power is supplied to the handpiece. The other modes are controlled through the user interface. Pre-cooling and treatment parameters are set from the user interface on the control unit. The interface screen also displays system information such as current operational mode and measurement of real-time temperature at the cooling plate. The minimum temperature is -30°C; the maximum treatment duration is 300 seconds. Following the cooling cycle, the contact surface is warmed either passively, or if selected by the user, actively during which time the contact surface is warmed to a pre-set temperature (maximum 5°C).

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 enter and display information; establishing communications with the TEC controller to monitor and control temperature; and monitoring and controlling treatment time/cycles.

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 temperature 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 fluid, providing cooled water to serve as a liquid heat exchange and 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 110 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Dermal Cooling System and the predicate devices are all cryosurgical instruments; the devices cool tissue to temperatures that can be used to freeze tissue in dermatologic procedures of the skin.

The subject device and the primary predicate device have these same technological elements:

- freezing tissue without the use of cryogenic liquids or gases;
- contact surface cooling at a targeted treatment site on the skin;
- treatment conditions suitable to generate cryoablation zone at targeted treatment site; and
- aluminum cooling interface within a medical grade plastic hand piece.

The technological differences that exist between the subject device and the primary predicate are:

- 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 use of a TEC to cool the aluminum contact surface does 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 use of software control is addressed by the secondary predicate, which has the same intended use as both the subject device and the primary predicate, and is a software-based cryosurgical system.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process (2009/Technical Corrigendum 1 2010), as recognized by FDA. The Dermal Cooling System is considered a skin contacting, surface device for limited duration ($\leq$ 24 hours). Cytotoxicity, sensitization, and irritation testing was performed.

Electrical safety, EMC, and usability testing were conducted in compliance with IEC 60601-1 (2005+A1:2012) for safety, IEC 60601-1-2 (2007) for EMC, and IEC 60601-1-6 (2010) standard for usability.

Bench testing to controlled protocols, with calibrated equipment, was used to demonstrate the ability of the Dermal Cooling System to meet performance specifications, and to demonstrate substantial equivalence. These tests included design verification, usability, and subsurface temperature measurements.

Verification testing was completed to demonstrate:

- thermistor and timer accuracy
- thermal performance
- thermal range
- reuse
- physical specifications
- compatibility with use environment
- treatment parameters (i.e., minimum and maximum temperature settings, treatment duration, active warming, auto-recipe),
- power and operational control,
- labeling, interface, and support requirements

Usability testing was performed by individuals who had no prior experience in the use of the Dermal Cooling System. Individuals were asked to read the Operating Guide and then perform a mock cooling procedure, multiple times, on a simulated test system. All users successfully completed the mock procedure and demonstrated understanding of the device features.

Substantial equivalence testing was performed with the Dermal Cooling System and the predicate CryoPen device to demonstrate that the cryoablation zone created with the Dermal Cooling System was equivalent to that of the predicate. An *in vitro* simulated model was used to allow the recording of subsurface measurements, with both devices used in accordance to its operating guide. Measurements documented with the *in vitro* model verified the creation of a substantially equivalent cryoablation zone with both devices.

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.

No preclinical or clinical testing was performed.

VIII. CONCLUSIONS

The Dermal Cooling System and the predicate devices have the same intended use; they are cryosurgical instruments intended for use to cool tissue to temperatures that freeze tissue in dermatologic procedures of the skin. The Dermal Cooling System has technological characteristics with features that are the same as some of those of the primary predicate (e.g., contact cooling without the use of cryogenic gas or liquid) and some of those of the secondary predicate (e.g., software control). The technological feature that is unique to the Dermal Cooling System, the use of a TEC to cool the

aluminum contact plate, does not raise new questions of safety and effectiveness for the intended use. The performance data demonstrate that the device performs to specification and is expected to be equivalent to the predicates, in safety and effectiveness, for the specified use conditions. All testing, including substantial equivalence testing with the primary predicate, was passed. The Dermal Cooling System is, therefore, determined to be substantially equivalent.