August 5, 2021

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

Re: K203006
Trade/Device Name: Dermal Cooling System
Regulation Number: 21 CFR 878. 4340
Regulation Name: Contact Cooling System for Aesthetic Use
Regulatory Class: Class II
Product Code: QPZ, GED
Dated: June 9, 2021
Received: June 11, 2021

Dear Ragan 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)*
K203006

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.

When the Dermal Cooling System is used with the R2 Dermabrasion Tips, the intended use includes general dermabrasion, scar revision, acne scar revision, and tattoo removal.

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

I. SUBMITTER

R2 Technologies, Inc.
2603 Camino Ramon, Suite 200
Bishop Ranch 3
San Ramon, CA 94583

Contact: Ms. Ragan Reppond
Vice President of Corporate Affairs & Compliance
R2 Technologies, Inc.
Phone: 925-378-4400

rreppond@r2technologies.com

Date Prepared: July 29, 2021

II. SUBJECT DEVICE and ACCESSORY

Device Name:	Dermal Cooling System
Device Common Name:	Contact cooling for skin lesion pain relief
Accessory Name:	R2 Dermabrasion Tips
Accessory Common Name:	Brush, Dermabrasion, Manual
Regulatory Class :	II
Product Code :	QPZ, GED
Regulation :	21 CFR 878.4340, 21 CFR 878.4800

III. PREDICATE AND REFERENCE DEVICES

The predicate device is the Dermal Cooling System, K201260.

Name of Device:	Dermal Cooling System
Common Name:	Cryosurgical unit and accessories
Regulatory Class:	II
Product Code:	GEH, MLY
Regulation:	21 CFR 878.4350

The reference device is the Derma Paddle (Livra) attachment (Class I, 510(k) exempt), manufactured by Procell Therapies.

IV. DEVICE DESCRIPTION

The Dermal Cooling System is identical to the device cleared in K201260. 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. For dermabrasion, the Dermal Cooling System handpiece is intended to serve as a handle to facilitate manual movement of the R2 Dermabrasion Tips.

The R2 Dermabrasion Tips are optional accessories for the Dermal Cooling System that may be attached to the distal end of the handpiece to facilitate manual dermabrasion. The R2 Dermabrasion Tips may be used with a commercially available topical or water to facilitate movement of the handpiece across the treatment area.

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.

When the Dermal Cooling System is used with the R2 Dermabrasion Tips, the intended use includes general dermabrasion, scar revision, acne scar revision, and tattoo removal.

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The predicate device, the Dermal Cooling System, has not been modified for use with the R2 Dermabrasion Tips and proposed expanded indication, i.e., general dermabrasion, scar revision, acne scar revision, and tattoo removal.

The reference device, the Derma Paddle (Livra) attachment, is included to substantiate the proposed expanded indications for use for the R2 Dermabrasion Tips as the intended use for the Derma Paddle (Livra) attachment (510(k) exempt) includes “general dermabrasion, scar revision, acne scar revision, and tattoo removal”. The R2 Dermabrasion Tips and the Derma Paddle (Livra) attachment have these same fundamental scientific technological elements:

The R2 Dermabrasion Tips and the reference device, Derma Paddle (Livra) attachment have these similarities:

- used for aesthetic purposes;
- fabricated from metal;

- textured surface (roughness);
- intended for manual dermabrasion;
- classification (generic description)

The key differences between the R2 Dermabrasion Tips and the Derma Paddle (Livra) attachment are:

- geometry
- mechanism of attachment

The differences do not raise new questions of safety and effectiveness with respect to the R2 Dermabrasion Tips and proposed expanded indication.

VII. PERFORMANCE DATA

Performance data is provided in support of the substantial equivalence determination, as summarized in the table below.

Dermabrasion performance test demonstrated the R2 Dermabrasion Tips can perform its intended use safely and effectively when used with the Dermal Cooling System, while the thermal insulation test supported the conclusion no additional risk was introduced when the R2 Dermabrasion Tips are used with the Dermal Cooling System.

Test	Test method/Requirement	Acceptance criteria	Results
Accessories Validation	Dermabrasion Performance Test: 3 subjects tested with the R2 Dermabrasion Tips (20 Amps EDM) and 3 subjects tested with (80 Amps EDM)	No unexpected side effects observed immediately post test, and 2-days post test	Passed
	Thermal Insulation Test: 3 subjects tested with the R2 Dermabrasion Tips (20 Amps EDM and 80 Amps EDM)	Skin temperature to remain at or above +20 ^{O}C for the full duration	Passed

No preclinical or clinical testing was performed.

VIII. CONCLUSIONS

An optional accessory, manual dermabrasion tips, is added to the Dermal Cooling System cleared in K201260. Performance tests demonstrated the dermabrasion tips can perform as intended when used with the Dermal Cooling System without introducing additional risks for the intended use. No new question of safety or effectiveness is raised. The subject device is therefore considered as substantially equivalent to the predicate device K201260.