GEHDEPARTMENT 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 6, 2016

Cool Renewal, LLC
% Ms. Audrey Swearingen
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
Austin, Texas 78701-2631

Re: K161296
Trade/Device Name: Cool Renewal
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 6, 2016
Received: May 9, 2016

Dear Ms. Swearingen:

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)*

K161296

Device Name
Cool Renewal

Indications for Use *(Describe)*

1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1- trifluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon (skin tags), molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K161296

1. Submission Sponsor

Name:	Cool Renewal, LLC
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Telephone:	615-844-0132
Fax:	615-544-1411
Contact person:	Ashley Rains, President

2. Submission Correspondent

Name:	Emergo
Address:	816 Congress Avenue, Suite 1400 Austin, Texas 78701 United States
Telephone:	512-327-9997
Fax:	512-327-9998
Contact person:	Audrey Swearingen (RAC), Director Regulatory Affairs
Email:	project.management@emergogroup.com

3. Date Prepared

July 5, 2016

4. Device Identification

Trade/Proprietary Name:	Cool Renewal®
Common/Usual Name:	Portable aerosol cryosurgery device
Classification Name:	Unit, Cryosurgical, Accessories
Classification Regulation:	878.4350
Product Code:	GEH
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Nuance Freeze Spray (K130995) manufactured by Nuance Medical, LLC is the primary predicate device.

6. Device Description

Cool Renewal® is used in the practice of dermatology in the treatment of benign skin lesions using a cryogen spray system. This methodology is an accepted practice used by physicians for decades using accepted procedures and techniques. It utilizes a standard cryogen composition profile to freeze common skin lesions.

The main device component is the aerosol canister containing cryogen spray. The device is used with non-sterile, single-patient applicators which are disposed after use. The applicators are available in Foam Tipped Applicators, Foam Tipped Skin Tag Tweezers, and Plastic Isolation Funnels. The device is provided in a kit containing the canisters, extender tubes, assorted applicators, Instructions for Use, Patient Instruction Tear Pad, and Applicator Practice Pad.

The mechanisms of action for any cryotherapy using R404A gas, including Cool Renewal® and the predicate device, Nuance Freeze Spray, are:

1. The direct effects of freezing on the cells, and
2. The vascular stasis which develops in the tissue after thawing.

During cryosurgery, both extracellular and intracellular ice formation occur, with fast freezing in the center of the lesion, and slow freezing on the outside border. The loss of blood supply to the treated area eradicates the likelihood of survival of the cells in the frozen tissue.

7. Indications for Use Statement of Cool Renewal®

1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1- trifluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon, molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyrogenic granuloma.

8. Substantial Equivalence Discussion

The Cool Renewal® intended use, indications and clinical application as well as device design, materials and overall technical characteristics are substantially equivalent to the predicate device. The below table compares the Cool Renewal® to the predicate device with respect to intended use, technological characteristics and principles of operation and provides detailed information regarding the basis for the determination of substantial equivalence (see Table 5A).

Differences between Cool Renewal® and the predicate device are related to minor design elements. The Cool Renewal® Foam Tipped Applicators are double-ended (strictly cosmetic difference). Cool Renewal® is provided with a third applicator (Foam Tipped Skin Tag Tweezers) which has been developed to effectively address the treatment of “skin tags” that tend to hang from the patient’s skin. The Cool Renewal® applicators are also disposable and intended for single-patient use. None of these differences raise any new questions about safety or effectiveness. It is concluded that Cool Renewal® is substantially equivalent to the predicate device manufactured by and Nuance Medical, LLC (Nuance Freeze Spray).

Table 5A – Comparison of Characteristics

Manufacturer	Cool Renewal, LLC	Nuance Medical, LLC	Significant Differences
Trade Name	**Cool Renewal®**	**Nuance Freeze Spray**	
510(k) Number	-	K130995	-
Product Code	GEH	GEH	Same
Regulation Number	878.4350	878.4350	Same
Regulation Name	Cryosurgical unit and accessories	Cryosurgical unit and accessories	Same
Indications for Use	1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1-trifluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon, molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.	1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1-trifluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon, molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.	Same
Mechanism of Action	Application of extreme cold causing tissue destruction due to: 1) Direct effects of freezing on the cells, 2) Vascular stasis which develops in the tissue after thawing.	Application of extreme cold causing tissue destruction due to: 1) Direct effects of freezing on the cells, 2) Vascular stasis which develops in the tissue after thawing.	Same
Cryogen Gas Material	R404A: 1,1,1,2-tetrafluoro-ethane (CAS 354-33-6); Pentafluoroethane (CAS 420-46-2); 1,1,1- trifluoroethane (CAS 811-97-2)	R404A: 1,1,1,2-tetrafluoro-ethane (CAS 354-33-6); Pentafluoroethane (CAS 420-46-2); 1,1,1- trifluoroethane (CAS 811-97-2)	Same
Freeze time	15-40 seconds	15-40 seconds	Same.
Applicators	Foam Tipped Applicator Plastic Isolation Funnel Foam Tipped Skin Tag Tweezer	Buds Dosing Cones	Similar. Cool Renewal® is supplied with a third applicator. Cool Renewal® Funnels are disposable. Does not add new safety or efficacy concerns.
Sterile	No	No	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Cool Renewal®, and substantial equivalence to the predicate device, comparative testing was performed on a "phantom skin model" to determine the degree of cold generated by the cryogen and the time frame that such temperatures are deemed "effective temperatures" for using cryosurgery. The comparison bench test studied temperature drop over time for the subject and predicate device applicators, measuring the temperature drop on the surface of the applicator portion placed over the wart or skin lesion after dispensing the cryogen onto the applicator. The test determined that Cool Renewal® cryogen and applicators perform equivalently to Nuance Freeze Spray cryogen and applicators by affecting equal surface area and depth during application. Further, it demonstrated that the device is capable of reaching the minimum desired temperature for the maximum treatment time of 40 seconds and performed comparably to the predicate device.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use are equivalent to those of the predicate devices. These types of devices have been on the market for decades and their clinical safety and efficacy has been established. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. While there are minor differences between the Cool Renewal® and its predicate device, these are related to cosmetic design. These differences do not affect the principle of operation or mode of action of the Cool Renewal®. Existing differences do not raise new questions regarding safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the minor differences between the Cool Renewal® and the predicate device do not raise any questions regarding its safety and effectiveness. The Cool Renewal® device is determined to be substantially equivalent to the predicate device, Nuance Freeze Spray.

12. Conclusion

The Cool Renewal® device, based on comparison to the predicate and the results of performance testing, is substantially equivalent to the predicate device, Nuance Freeze Spray.