March 25, 2020

Brymill Cryogenic Systems
% Roshana Ahmed
Sr. Consultant, Regulatory Affairs, Medical Devices
G&L Scientific, Inc.
25 Independence Blvd., Suite 404
Warren, New Jersey 07059

Re: K193619
Trade/Device Name: Cry-Ac®, Cry-Ac-3®, Cry-Baby
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 19, 2019
Received: December 26, 2019

Dear Roshana Ahmed:

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)*
K193619

Device Name
Cry-Ac(R)
Cry-Ac-3(R)
Cry-Baby(R)

Indications for Use *(Describe)*

The Cry-Ac® Cryosurgical Devices and Accessories are intended for use as cryosurgical tools in the field of dermatology. The Cry-Ac® Cryosurgical Devices and Accessories are indicated for:

• Ablation or freezing of skin cancers and other cutaneous disorders
• Destruction of skin tags, warts or lesions, angiomas, sebaceous hyperplasia, basal cell carcinoma, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, perianal condylomata, and palliation of tumors 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

I. Submitter

Brymill Cryogenic Systems
105 Windermere Avenue, Suite 2B
Ellington, CT 06029
Phone: 800-777-2796 x 103

Contact Person: Paul Sideleau, Senior Quality Assurance and Regulatory Manager
Date Prepared: March 13, 2020

II. Device

Device Proprietary Names:	Cry-Ac®, Cry-Ac-3®, Cry-Baby®
Common or Usual Name:	Cryosurgical Unit and Accessories
Classification Name:	Cryosurgical Unit and Accessories
Regulation Number:	21 CFR 878.4350
Product Code:	GEH
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary predicate
  - Cry-Ac B-700 and B-800 and Accessories, Pre-Amendments Devices, Brymill Corporation

- Secondary predicates
  - SeedNet™ System and SeedNetGold™ System, K031117, Galil Medical Ltd.
  - CryoPro® Mini and CryoPro® Maxi, K982280, Cortex Technology ApS
  - Wallach Ultra Freeze, K935010, Wallach Surgical Devices Inc.

IV. Device Description

The Cry-Ac® Cryosurgical Devices (Cry-Ac®, Cry-Ac-3®, and Cry-Baby®) are hand-held, re-fillable, cryosurgical devices which dispense pressurized liquid nitrogen via open spray and closed probe applicators.

The cryosurgical devices are provided in three (3) sizes: 4 oz (125 mL; Cry-Baby®), 10 oz (300 mL, Cry-Ac-3®), and 16 oz (500 mL; Cry-Ac®). The open spray applicators include apertures, bent and straight spray extensions (1 in and 3 in), and cryochambers (6 mm to 18 mm) in various gauges. The probe applicators include mini probes (1 mm to 6 mm), conical probes (1 mm to 6

mm), ball probes (6 mm to 3 cm) and flat probes (8 mm to 3 cm). Additional accessories include a back-vent adapter, luer lock adapter, malleable extension, and right-angle and 45° adapters. The apertures are manufactured from brass, the probes are manufactured from stainless steel and brass, and coated with Teflon. Extension tubing is manufactured from silicon.

The Cry-Ac® Cryosurgical Devices, open spray and closed probe applicators, and adapters are provided non-sterile and are autoclavable.

V. Indications for Use

The Cry-Ac® Cryosurgical Devices and Accessories are intended for use as cryosurgical tools in the field of dermatology. The Cry-Ac® Cryosurgical Devices and Accessories are indicated for:

- Ablation or freezing of skin cancers and other cutaneous disorders
- Destruction of skin tags, warts or lesions, angiomas, sebaceous hyperplasia, basal cell carcinoma, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, perianal condylomata, and palliation of tumors of the skin

VI. Comparison of Technological Characteristics

The Cry-Ac® Cryosurgical Devices and Accessories have the same intended use as the SeedNet™ System and SeedNetGold™ System (K031117) and CryoPro® Mini and CryoPro® Maxi (K982280). Slight differences in the indications for use statements do not alter the overall intended use of the subject devices with respect to the predicate devices.

The Cry-Ac® Cryosurgical Devices and Accessories are technologically similar to the Cry-Ac B-700 and B-800 and Accessories (Pre-Amendments Devices), CryoPro® Mini and CryoPro® Maxi (K982280), and Wallach Ultra Freeze (K935010).

The Cry-Ac® Cryosurgical Devices and the predicate devices share the following technological characteristics:

- use of a self-pressurizing, untethered cryosurgical liquefied gas coolant delivery system;
- use of insulated bottles and inclusion of relief valves;
- delivery of liquid nitrogen;
- use of metal reservoir to store liquid nitrogen;
- use of a finger trigger to release liquid nitrogen;
- use of a soldered reservoir/collar connection for Cry-Baby®, and
- use of a vent in the reservoir cap as a fail-safe mechanism for pressure relief.

The Cry-Ac® Cryosurgical Devices are technologically different from the predicate devices as follows:

- provision of smaller reservoir volumes to provide for different storage capacities, and
- use of adhesive (instead of soldering) for the Cry-Ac® and Cry-Ac-3® reservoir/collar connection.

The Cry-Ac® Cryosurgical Accessories and the predicate devices share the following characteristics:

- provision of open sprays (apertures, straight sprays, bent sprays, and cryochambers) and closed probes (mini probes, conical probes, ball probes, and flat probes);
- same materials of construction;
- same sizes; and
- reprocessing via steam sterilization.

There are no technological differences between the Cry-Ac® Cryosurgical Accessories and the predicate devices.

Technological comparison

	Cry-Ac® Cryosurgical Devices and Accessories	**Cry-Ac® Cryosurgical Devices and Accessories (Pre-Amendment Device)**	**Wallach Ultra Freeze (K935010)**	**CryoPro® Mini and CryoPro® Maxi (K982280)**
Manufacturer	Brymill Cryogenic Systems	Brymill Corporation	Wallach Surgical Devices, Inc. (now Cooper Surgical)	Cortex Technology ApS
Delivery System	Self-pressurizing, untethered cryosurgical liquified gas coolant delivery system	Self-pressurizing, untethered cryosurgical liquified gas coolant delivery system	Self-pressurizing, untethered cryosurgical liquified gas coolant delivery system	Self-pressurizing, untethered cryosurgical liquified gas coolant delivery system
Gas	Liquid nitrogen	Liquid nitrogen	Liquid nitrogen	Liquid nitrogen
Volume	4 oz (125 mL; Cry-Baby®) 10 oz (300 mL, Cry-Ac-3®)	16 oz (500 mL)	.3 L (300 mL) .5 L (500 mL)	.35 L (350 mL) .5 L (500 mL)

	16 oz (500 mL; Cry-Ac®)			
Reservoir	Reusable double walled metal vacuum bottle	Metal canister to hold liquid nitrogen	Reusable insulated metal pressure vessel	Reusable insulated metal pressure vessel
Open Sprays	Apertures Straight Sprays Bent Sprays Cryochambers	Apertures Straight Sprays Bent Sprays Cryochambers	Apertures	Apertures Straight Spray Bent Spray Soft Peel Spray
Closed Probes	Mini probes Conical probes Ball probes Flat probes	Mini probes Conical probes Ball probes Flat probes	Closed Tips (4)	Mini probes Conical probes Flat probes

VII. Performance Data

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

- cleaning validation;
- sterilization validation per ANSI/AAMI/ISO 17665-1:2006;
- shelf-life testing;
- biocompatibility testing per ISO 10993-5:2009 and ISO 10993-10:2012;
- reservoir/collar bond verification and validation test;
- finger trigger validation; and
- temperature testing.

VIII. Conclusion

The information provided above supports that the Cry-Ac® Cryosurgical Devices and Accessories are as safe and effective as the predicate devices. Although minor differences in design and technology exist between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the Cry-Ac® Cryosurgical Devices and Accessories are substantially equivalent to the predicate devices.

----------This space intentionally left blank----------