October 31, 2019

DGI Technologies
% Russ Olsen
VP Global QA/RA
Health Policy Associates
690 Canton Street, Suite 302
Westwood, Massachusetts 02090

Re: K190747
Trade/Device Name: Claritag
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: March 20, 2019
Received: March 22, 2019

Dear Russ Olsen:

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)*
K190747

Device Name
Claritag

Indications for Use *(Describe)*
Claritag is indicated for use in the treatment of achrochordons (skin tags).

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.

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510(k) Summary

Prepared in accordance with 21 CFR 807.92

GENERAL INFORMATION

510(k) owner name address and telephone:

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Lakewood, NJ 08701
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Telephone: 732-887-5087

Name of contact person info:

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Date Prepared: October 30, 2019

DEVICE INFORMATION:

Trade Name:	Claritag®
Common Name:	Portable aerosol cryosurgery device
Classification Name:	Cryosurgical Unit and Accessories
Regulation Number:	21 CFR 878.4350
Regulatory Class:	Class II
Product Code:	GEH

PREDICATE DEVICE INFORMATON:

Trade Name:	Cool Renewal
Common Name:	Cryosurgical Unit and Accessories
510(k) Number:	K161296
Decision Date:	February 9, 2011

DEVICE DESCRIPTION:

The Claritag device is indicated for the treatment of skin tags. Claritag® is a portable, hand operated device intended for use in the treatment of skin tag removal using a cryogen application system. The cryogen application methodology for skin tag removal is a widely accepted practice used by physicians for decades.

The Claritag device is provided in a kit containing the main device (canister containing aerosolized cryogen, fitted with two treatment heads), a treatment head activation base, 20 disposal single use foam pads, tweezers (which are provided as an optional accessory) and Instructions for Use.

The mechanism of action for cryotherapy are the direct effects of freezing on the cells, and the vascular stasis which develops in the tissue after thawing.

INTENDED USE OF CLARITAG

The Claritag device is indicated for use in the treatment of acrochordons (skin tags).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use and principles of operation of the Claritag device are substantially equivalent to the predicate device. Both devices incorporate the same basic cryosurgical design for skin tag removal, i.e., two foam pads treated with cryogen that enclose the skin tag and, after brief exposure, freezes the skin tag. The skin tag then thaws, and ultimately the skin tag tissue is destroyed. Both the Claritag device and the predicate achieve the minimum *freeze temperature* of -20°C, the widely accepted temperature required to destroy skin tags.

The differences between the Claritag device and the predicate are related to the cryogenic gas, and minor design elements. The Claritag device uses an alternative gas, which is more environmentally friendly versus the predicate device's cryogen gas. The Claritag device incorporates a dual head design with foam pads which wrap around, squeeze and freeze the skin tag. The predicate device uses "foam tipped skin tag tweezers" to wrap around, squeeze and freeze the skin tag. Any other differences are considered to be minor in nature and do not raise any new questions about safety and effectiveness.

PERFORMANCE DATA

The following non-clinical performance data are provided in support of the substantial equivalence determination:

Biocompatibility:
- Cytotoxicity
- Sensitization
- Irritation

Performance testing
- Claritag Predicate Comparison: The temperature of the foam pads of the Claritag device and the predicate device were measured ten times using a simulated skin model. Both Claritag device and predicate device measurements met the minimum temperature requirement of -20 °C.
- Claritag Ballistic Gel Test: Depth of temperature penetration of the Claritag device was measured at 1, 2 and 3 mm from the outer face of the ballistic gelatin. This test confirmed that the Claritag device's cryogenic gas freezing effect decreases with depth and demonstrates the safety and effectiveness of the Claritag in the treatment of acrochordons (skin tags).
- Shelf Life: The Claritag device has real time data that represents a one-year shelf life consistent with the predicate device.
- Package Performance Testing for Claritag: The Claritag device passed package performance testing pursuant to ISTA 6 -Fed Ex-A.
- Claritag & Predicate Pad Temperature Comparison Test: Temperature testing of the Claritag device and the predicate device both achieved an average minimum temperature of -20 °C.

Conclusion:

The non-clinical performance data demonstrate that the Claritag device performs comparably to the predicate device that is currently marketed for the same intended use. Based upon the information submitted in this Traditional 510(k) premarket notification, the Claritag device is substantially equivalent to the Cool Renewal (K161296).