June 02, 2023

DGI Technologies
% Marc C. Sanchez, Esq.
Regulatory Counsel
Contract In-House Counsel and Consultants, LLC (d/b/a FDA Atty)
1717 Pennsylvania Ave NW
Suite 1025
Washington, District of Columbia 20006

Re: K222356
Trade/Device Name: Claritag Advanced
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH

Dear Marc Sanchez:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 18, 2023. Specifically, FDA is updating this SE Letter as an administrative correction, to revise the incorrect contact information on the original SE letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Trumbore, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-5436, Mark.Trumbore@fda.hhs.gov.

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.02 08:21:45 -04'00'

Mark Trumbore, 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

May 18, 2023

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

Re: K222356
Trade/Device Name: Claritag Advanced
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: April 19, 2023
Received: April 19, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.18 11:19:29 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222356

Device Name
Claritag Advanced

Indications for Use *(Describe)*
The Claritag Advanced is intended for the OTC treatment of skin tags in adults age 21 years or older.

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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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."

DGI Group
Traditional 510(k)
Claritag

510(k) Summary

The following information is provided as required by 21 CFR 807.92 for the Claritag Advanced 510(k) premarket notification.

Trade Name of Device:	Claritag Advanced
Common Name of Device:	Portable aerosol cryosurgery device
Sponsor:	DGI Group, LLC 400 Candelwood Commons Howell, **NJ** 07731 Telephone: 732-887-5087
Contact person:	Marc C. Sanchez, Esq. Regulatory Counsel 1717 Pennsylvania Ave. NW, Suite 1025 Washington, D.C. 20006 (202) 765-4491 msanchez@fdaatty.com

Date: May 17, 2023
Device Class: II
Regulation Name and Number: 878.4350
Panel: Office of Health Technology 4, Division of Health Technology 4 A Product Code: GEH
Predicate: K211099

Device Description

The Claritag Advanced 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 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.

The **Claritag® Kit** contains the **Claritag** handheld device and the **Claritag Base**. The

Claritag device houses the **Claritag®** "squeeze and freeze" heads with foam treatment pads and liquid cooling gas. A spare set of treatment heads is included.

The Claritag Base will activate the freezing once the heads are placed into the base. Pressing down on the base sends the liquid cooling gas to the Claritag "squeeze and freeze heads." Instructions for Use are included.

Intended Use:

The Claritag Advanced is intended for the OTC treatment of skin tags in adults age 21 years or older.

Non-Clinical Test Reports

The following tests were performed on the Claritag Advanced device and the test results show that the subject device is substantially equivalent to the predicate Device.

Biocompatibility:
- Cytotoxicity
- Sensitization
- Irritation

Performance testing
- Mechanical Integrity Testing (as outlined in ASTM F882-84(2002)
- Effective Duration Test
- Temperature Testing

Human Factors: A human factors validation test was performed on the Claritag Advanced device and the test results show that the subject device is substantially equivalent to the predicate Device.

Summary of Substantial Equivalence

The Claritag Advanced and the predicate are for similar uses and rely on the same mode of action. Both devices use cryogenic gases. The cryogenic gas in the Claritag Advanced device was chosen as HP152A due to its safety characteristics as compared with DMEP ("DME") in the Freeze'n Clear device.

Table 1
Technological Characteristics

	Subject Device	Primary Predicate	Secondary Predicate
	Claritag (OTC)	Freeze'n Clear Skin Clinic Warts & Tags	Claritag (Rx)
	DGI Technologies	CryoConcepts (sold by Dr. Scholl's)	DGI Technologies
Characteristic	K222356	K211099	K190747
Intended Use	Skin Tags	Warts & Skin Tags	Skin Tags
	OTC	OTC	Rx
Cryogen	HP152a	DMEP	HP152a
Contents	Canisters containing cryogen	Canister containing cryogen	Canisters containing cryogen
	Foam tips in plastic holder to protect surrounding skin	Foam applicator	Foam tips in plastic holder to protect surrounding skin
		Tweezers to hold up skin tag	
Mechanism of Action	Extreme cold freezes skin tag	Extreme cold freezes skin tag or wart	Extreme cold freezes skin tag
Time to freeze skin tag	20 seconds, 2 times	40 seconds	20 seconds, 2 times
Visible safety indicator of freezing temperature	Blue tint in foam pads	None	Blue tint in foam pads
Safety Conditions	Do not puncture or destroy gas canister	Do not puncture or incinerate gas canister	Do not puncture or destroy gas canister
	Flammable aerosol. Pressurized canister. May burst if heated. Do not expose to temperatures exceeding 400C/1200F	Do not expose to heat or store at temperatures above 1200F	Flammable aerosol. Pressurized canister. May burst if heated. Do not expose to temperatures exceeding 400C/1200F
	Do not smoke or use near an open flame	Do not smoke while using the product. Keep away from fire or flame.	Do not smoke or use near an open flame
Treatment Procedure	Push down on the canister until hissing sound starts and stops and foam tips turn blue. Place the tips around the tag and squeeze for 20 sec. Repeat.	Spray the cryogen into the applicator to saturate it and then place it directly onto the lesion for 40 sec.	Push down on the canister until hissing sound starts and stops and foam tips turn blue. Place the tips around the tag and squeeze for 20 sec. Repeat.
Number of Treatments	10	8	10
Disposal	Entire unit is disposable after emptied of cryogen	Entire unit is disposable after emptied of cryogen	Entire unit is disposable after emptied of cryogen
Service/Repair	None	None	None

Outer Box Label - Intended Use	Skin Tag Removal Device	Skin Tag Remover in as little as 1 treatment	Skin Tag Removal Device
Outer Box Label - Exclusion Criteria	Do not use if you are diabetic, have poor blood circulation, or have been diagnosed with blood conditions affected by extreme cold or if younger than 18 years old	Do not use if you are diabetic, have poor blood circulation, or have been diagnosed with blood conditions affected by extreme cold or if younger than 21 years old	Do not use if you are diabetic, have poor blood circulation, or have been diagnosed with blood conditions affected by extreme cold
Outer Box Label - Warnings	Keep out of reach of children. For External Use Only.	Keep out of reach of children. For External Use Only.	Keep out of reach of children. For External Use Only.
	Flammable Aerosol. Presurized container. May burst if heated. Keep away from hot surfaces, sparks open flames and other ignition sources. Do not expose to temperatures exceeding 400C/1200F. (Inside labeling includes all the other predicate warnings.)	Avoid contact with eyes. Avoid inhaling and use only in well ventilated areas. Do not eat. For external use only. Use only as directed. Do not spray gas directly onto skin. Misuse of this product may result in burns and scarring of healthy tissue or blindness.	Flammable Aerosol. Presurized container. May burst if heated. Keep away from hot surfaces, sparks open flames and other ignition sources. Do not expose to temperatures exceeding 400C/1200F. (Inside labeling includes all the other predicate warnings.)
Biocompatibility	Meets ISO 10993 Requirements	Meets ISO 10993 Requirements	Meets ISO 10993 Requirements

Conclusion:

Therefore, taking into consideration Table 1 for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the Claritag Advanced raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate device.