December 30, 2020

Vitreq B.V.
% Debora Stapleton
Regulatory Affairs Consultant
Dynamic Strategies Inc.
25 Granite Street
Medway, Massachusetts 02053

Re: K202038
Trade/Device Name: CryoTreQ
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic unit
Regulatory Class: Class II
Product Code: HPS
Dated: November 23, 2020
Received: November 24, 2020

Dear Ms. Stapleton:

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,

for LT Charles Chiang
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K202038

Device Name
CryoTreQ

Indications for Use *(Describe)*
The VitreQ CryoTreQ is indicated for use in ophthalmic surgery such as cryopexy for retinal detachment, cyclodestructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, cryodestruction of lash follicles for trichiasis and the treatment of retinopathy of prematurity (ROP).

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.

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510(k) Summary

Submitter's Information

Submitter: Vitreq BV
Seggelant-Noord 2
Vierpolders Zuid-Holland, NL 3237 MG

Contact Person: Debora Stapleton
Telephone Number: 774-277-2320
Date Prepared: 12/30/2020

Name of the Device

Trade or Proprietary Device Name: CryoTreQ
Common Name: Cryophthalmic Unit
Classification Name: Cryophthalmic Unit
Classification Regulation: 21 CFR 886.4170
Product Code: HPS, Class II

Legally Marketed Predicate

Primary Predicate Device Name: D.O.R.C. Cryo Unit, 510(k) Number K940373
Secondary Predicate Device Name: Keeler Cryomatic MKII Cryosurgical System, 510(k) Number K131787
Reference Predicate Device Name: PHAKOS Disposable Retinal Cryo Probe, 510(k) Number K162756

Description of Subject Device

The VitreQ CryoTreQ is a disposable, handheld instrument intended for use in ophthalmic cryotherapy. The device tip is made of stainless steel. The device utilizes a pressurized cryogen which is circulated to the tip. The cryogenic material remains enclosed within the tip during application, serving to cool the metal tip during therapy. Rapid gas expansion in the tip causes freezing according to the Joule-Thompson principle.

Intended Use

The device is intended for patients suffering from eye disease which are diagnosed to have a condition or conditions which may benefit from ophthalmic cryotherapy.

Indications for Use

The VitreQ CryoTreQ is indicated for use in ophthalmic surgery such as cryopexy for retinal detachment, cyclodestructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, cryodestruction of lash follicles for trichiasis and the treatment of retinopathy of prematurity (ROP).

Summary of Technological Characteristics

The CryoTreQ has materials, basic design, and cryogen type which are the same as for the predicate. The operational mechanism is the same; cryogenic material moves toward a closed metal tip and remains within the metal cavity during application, serving as a means to cool the tip.

Comparison to Predicate - Technological Differences

The differences between the CryoTreQ and predicate cryotherapeutic devices are that the CryoTreQ is a fully disposable unit and the cryogenic function does not require connection to other devices. The predicate devices utilize connection of a handpiece (or probe), a footswitch (or footpedal) to an electronic console for activation, and a compressed gas cylinder for cryogenic function. The CryoTreQ is self contained. The cryogen-containing canister is supplied within the instrument for single procedure use.

Table Comparison of Features of VitreQ CryoTreQ and Predicate Devices

Characteristic	***VitreQ CryoTreQ***	***D.O.R.C. Cryo Unit***	***Keeler Cryomatic MKII Cryosurgical System***	***PHAKOS Disposable Retinal Cryo Probe***
510(k) Number	K202038	K940373	K131787	K162756
Product Code(s)	HPS	HPS	HRN	HRN
Intended Use	Ophthalmic cryotherapy	Ophthalmic cryotherapy	Ophthalmic cryotherapy	Ophthalmic cryotherapy
Operation Mechanism	Cooled metal contact	Cooled metal contact	Cooled metal contact	Cooled metal contact
Non-clinical Freeze and Defrost Testing	Pre-specified criteria were met	Not evaluated	Comparisons to CryoTreQ – external temperature achieved, ice ball formation, defrost duration, and traction	
Activation Method	Button activation	Footswitch activation	Footswitch activation	Footswitch activation
Electrical Source for Activation	None	Battery	Mains	Mains
Cryogen Supply Format	Internal compressed gas canister	External compressed gas cylinder	External compressed gas cylinder	External compressed gas cylinder
Cryogenic Medium	N2O gas	CO2 or N2O gas	CO2 or N2O gas	CO2 or N2O gas
Disposable or Reusable	Disposable unit	Reusable probes	Disposable and reusable probes	Disposable probe

Summary of Clinical Testing

No clinical studies were performed.

Summary of Non-Clinical Testing

Testing performed to evaluate the device included evaluations of the device activation mechanism, external temperature achieved, ice ball layer thickness formation, freezing events, defrost performance, dimensional analyses, device sterility, shelf life, evaluation of traction, bio-compatibility, ventilation safety, usability, transport stability, and sterile barrier integrity.

The body of testing performed on CryoTreQ devices demonstrated that they perform as well as the identified legally marketed devices.