December 5, 2019

Quantel Medical
% Maureen O'connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180

Re: K191962
Trade/Device Name: Vitra 2
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 31, 2019
Received: November 4, 2019

Dear Maureen O'Connell:

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 control's 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 Tieuvi Nguyen, Ph.D.
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)*
K191962

Device Name
Vitra 2®

Indications for Use *(Describe)*
The Vitra 2 is for use in the treatment of ocular pathology of anterior and posterior segments including retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroids including:

- Proliferative and nonproliferative diabetic retinopathy
- Choroidal neovascularization
- Branch retinal vein occlusion
- Treatment of choroidal neovascularization associated with wet Age-related macular degeneration
- Retinal tears and detachments
- Macular edema

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.

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510(k) SUMMARY
K191962

Quantel Medical
Vitra 2®

510(k) Owner

Quantel Medical
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France
Phone: 33 04 73 745 732
Contact Person: Bruno Pagès

Submission Correspondent:

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: November 25, 2019

Trade Name of Device

Vitra 2 ®

Common or Usual Name

Ophthalmic Lasers

Classification Name

Lasers, Ophthalmic; 21 C.F.R. 878.4810
Class II
Product Code: GEX

Predicate Device

Quantel Medical Vitra Multispot (K122251)

Device Description

The Vitra 2 is a laser system which emits a treatment beam at 532 nm and is intended for use in photocoagulation of ocular tissues in the treatment of diseases of the eye.Laser energy is delivered to opaque structures within the eye by means of delivery systems including slit lamp, indirect ophthalmoscope, operating microscope and endocular probe. The standard delivery system includes a lens system to focus the laser energy and vary the size of the laser

spot in the plane of observation of the slit lamp, for example. It also includes a Multispot delivery system made by scanner motors which can deliver several spots to the retina in a pattern. The laser energy is delivered to the delivery system by the means of a flexible fiber optic. For most procedures, a laser contact lens is used to direct the laser energy to the part of the eye being treated. The contact lens also helps to hold the eye open and still so that the laser energy can be delivered effectively.

The Quantel Medical VITRA 2 includes a Scanning Laser Delivery System adaptor with scanner controls that may be coupled to a slit lamp. Once activated by the user, the VITRA 2 delivers a predetermined pattern by sequentially scanning the placement of the laser spots and the emission of the individual pulses of laser light. Treatment is initiated by pressing the footswitch and may be aborted by releasing the footswitch.

Intended Use / Indications for Use

The Vitra 2 is for use in the treatment of ocular pathology of anterior and posterior segments including retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroids including:

- Proliferative and nonproliferative diabetic retinopathy
- Choroidal neovascularization
- Branch retinal vein occlusion
- Treatment of choroidal neovascularization associated with wet Age-related macular degeneration
- Retinal tears and detachments
- Macular edema

Substantial Equivalence

Quantel Medical believes that the Vitra 2 described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device regulated under product code GEX (21 C.F.R. 878.4810) . The predicate device is the Quantel Medical Vitra Multispot laser system cleared by FDA in K122251 and intended for use in photocoagulation of the posterior and anterior segments of the eye.

Both the Vitra 2 and the Vitra Multispot devices are intended for use in photocoagulation of the posterior and anterior segments. Additionally, both devices have the identical indications for use statement. Both devices are prescription devices which are intended to be used by trained medical personnel.

As shown in the table below, the Vitra 2 and the Vitra Multispot have the same technological characteristics. Both devices are frequency doubled Nd:YAG lasers with a wavelength of 532 nm. The maximum power at the tissue is 1500 mW for both systems with a pulse duration of 10 ms to continuous for both systems and the identical pulse repeat interval. Both the Vitra 2 and the Vitra Multispot use an aiming laser with a wavelength of 635-650 nm. Both systems are cooled by Peltier effect.

For the Single Spot Slit Lamp Adapters, the emission modes available in both the Vitra 2 and the Vitra Multispot are single, repeat, painting and continuous with an identical spot size of 50 to 500 microns. For the MultiSpot Slit Lamp Adapters in the Multispot Mode, the emission modes available in both the Vitra 2 and the Vitra Multispot are square, circle, triple arcs and single spot. For the MultiSpot Slit Lamp Adapters in the Monospot Mode, the spot modes available in both the Vitra 2 and the Vitra Multispot are single, repeat, painting and continuous. For the MultiSpot Slit Lamp Adapters, both the Vitra 2 and the Vitra Multispot are compatible with the same slit lamps and laser systems except the Vitra 2 is also compatible with the CSO 9800. Both systems can be used with the Keeler Vantage Plus laser indirect ophthalmoscope. The Vitra 2 can also be used with a commercially available sterile laser probe.

Therefore, as the Vitra 2 and the Vitra Multispot have the same intended use and similar technological characteristics, the Vitra 2 is substantially equivalent to the Vitra Multispot.

SPECIFICATIONS		
MANUFACTURER	QUANTEL MEDICAL	QUANTEL MEDICAL
510(K)	-	K122251
TYPE OF DELIVERY SYSTEM	Slit lamp Indirect ophthalmoscope Endocular probe Operating microscope	Slit lamp Indirect ophthalmoscope Operating microscope
PULSING SYSTEM	Continuous	Continuous
LASER SOURCE	Frequency doubled Nd:YAG	Frequency doubled Nd:YAG
WAVELENGTH	532 nm	532 nm
MAXIMUM POWER	1500mW (at tissue)	1500mW (at tissue)
PULSE DURATION	10 ms to continuous	10 ms to continuous
REPEAT INTERVAL	0.1 – 0.2 – 0.3 -0.5 – 0.7s	0.1 – 0.2 – 0.3 -0.5 – 0.7s
AIMING BEAM WAVELENGTH	635 – 650 nm	635 – 650 nm
Delivery System-Single Spot Slit Lamp Adapters		
SPOT MODE	Single, repeat, painting, continuous	Single, repeat, painting, continuous
SPOT SIZE	50 µm to 500 µm	50 µm to 500 µm
Delivery System-MultiSpot Slit Lamp Adapters		
MONOSPOT MODE		
EMISSION MODES	Single, repeat, painting, continuous	Single, repeat, painting, continuous
SPOT SIZE	50 µm to 400 µm	50 µm to 500 µm
MULTISPOT MODE		
EMISSION MODES	Square, circle, triple arcs, single spot	Square, circle, triple arcs, single spot
SPOT SIZE	100 µm to 400 µm	100 µm to 500 µm
RESUME FUNCTION	Yes	Yes

Performance Data

Performance testing was conducted in order to demonstrate compliance with recognized consensus standards and to demonstrate substantial equivalence:

- IEC 60601-1:2005 + Corr. 1:2006+Corr. 2:2007+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014: Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60601-1-6:2010+A1:2013 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability
- IEC 60601-2-22: 2007 (Third Edition) + A1:2012 Medical Electrical Equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1 Safety of Laser Products-Part 1: Equipment Classification and Requirements

Additionally, hardware and software validation activities were performed to ensure the device performed as intended and software documentation appropriate for the level of concern was provided.

In summary, the performance testing provided shows that the device performs as intended and is substantially equivalent to the predicate device.