August 6, 2020

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

Re: K201502
Trade/Device Name: Vitra 810
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: June 4, 2020
Received: June 5, 2020

Dear Ms. 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 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,

Elvin Ng
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)*
K201502

Device Name
Vitra 810

Indications for Use *(Describe)*
The Vitra 810 is intended for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following:

- Retinal photocoagulation for the treatment of:
  - o Diabetic retinopathy including:
    - Nonproliferative retinopathy
    - Macular edema
    - Proliferative retinopathy
  - o Retinal Tears, Detachments and Holes
  - o Lattice degeneration
  - o Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
  - o Retinopathy of prematurity
  - o Sub-retinal (choroidal) neovascularization
  - o Central and Branch Retinal Vein Occlusion

- Laser Trabeculoplasty, Iridotomy, Transscleral Cyclophotocoagulation for the treatment of glaucoma, including:
  - o Primary open angle
  - o Closed angle
  - o Refractory Glaucoma (recalcitrant/uncontrolled)

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
K201502

Quantel Medical
Vitra 810®

510(k) Owner

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Submission Correspondent:

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Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: August 4, 2020

Trade Name of Device

Vitra 810 ®

Common or Usual Name

Powered Surgical Laser

Classification Name

Powered Laser Surgical Instrument; 21 C.F.R. 886.4390
Class II
Product Code: HQF

Primary Predicate Device

Quantel Medical Supra Twin Ophthalmic Laser (K081946)

Product Code: HQF

Secondary Predicate Device

Iridex IQ 810 (K071687)

Product Code: GEX

Device Description

The Vitra 810 is a laser system which emits a treatment beam at 810 nm and is intended for use in photocoagulation of ocular tissues in the treatment of diseases of the eye. The laser is used to treat the retinal diseases and glaucoma.

The Vitra 810 is a laser system which emits a treatment beam at 810 nm and is intended for use in photocoagulation of ocular tissues in the treatment of diseases of the eye. The laser is used to treat the anterior and posterior segments of the eye. The laser is particularly well suited for treating the eye because it has minimal effect on transparent tissues and materials. This means that the laser can be efficiently delivered to opaque structures of the eye through the transparent cornea, aqueous humor, lens, and vitreous humor. This allows many conditions to be treated by non-invasive techniques.

Laser energy is delivered to opaque structures within the eye by means of laser delivery systems including slit lamp, indirect ophthalmoscope, operating microscope, cyclophotocoagulation probe and laser 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. 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 may have mirrors so that laser energy can be delivered to areas of the retina behind the iris, or into the angle so that the trabecular meshwork can be treated. The contact lens also helps to hold the eye open and still so that the laser energy can be delivered effectively.

Intended Use / Indications for Use

The Vitra 810 is intended for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following:

- Retinal photocoagulation for the treatment of:
    - Diabetic retinopathy including:
        - Nonproliferative retinopathy
        - Macular edema
        - Proliferative retinopathy
    - Retinal Tears, Detachments and Holes
    - Lattice degeneration
    - Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
    - Retinopathy of prematurity
    - Sub-retinal (choroidal) neovascularization
    - Central and Branch Retinal Vein Occlusion
- Laser Trabeculoplasty, Iridotomy, Transscleral Cyclophotocoagulation for the treatment of glaucoma, including:
    - Primary open angle
    - Closed angle

- Refractory Glaucoma (recalcitrant/uncontrolled)

Substantial Equivalence

Quantel Medical believes that the Vitra 810 described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to legally marketed predicate devices that are Class II medical devices. The primary predicate device is the Quantel Medical Supra Twin Ophthalmic Laser cleared by FDA in K081946. The secondary predicate device is the Iridex IQ 810 laser system cleared by FDA in K071687. All three devices are intended for use in photocoagulation of ocular tissue including the retina and pigmented tissue. All three devices are prescription devices which are intended to be used by trained medical personnel. Therefore, the Vitra 810 has the same intended use as the identified primary predicate device and an identical indications for use statement to the secondary predicate device and may be found to be substantially equivalent to the predicate devices.

As shown in Table 1, the Vitra 810, the Supra Twin and the Iridex IQ 810 have the same technological characteristics. All three devices are laser diodes with a wavelength of 810 nm. The treatment power ranges from 50-3000 mW for all three devices. The pulse duration is 10 ms to continuous (up to 60 seconds) for continuous wave mode in the Vitra 810, the Supra Twin and Iridex IQ 810. For the Subthreshold mode the pulse duration is 0.1 ms to 1.0 ms with a 5% to 35% duty cycle which is within the pulse duration range for the Iridex IQ 810 which is 0.025 ms to 1.0 ms (0.5% to 50% duty cycle). All three device use an aiming laser with a wavelength of 635-650 nm with a 1 mW maximum power.

All the systems are compatible with a variety of delivery systems including a slit lamp, indirect ophthalmoscope, operating microscope, laser probes and cyclophotocoagulation probes.

Therefore, the Vitra 810 and the primary predicate device, the Quantel Medical Supra Twin, supported by the Iridex IQ810 secondary predicate device, have the same intended use and similar technological characteristics and are therefore substantially equivalent.

Table 1

Vitra 810 Substantial Equivalence

	SPECIFICATIONS		
MANUFACTURER	QUANTEL MEDICAL	QUANTEL MEDICAL	IRIDEX
DEVICE NAME	Vitra 810	Supra Twin	IQ 810
510(K)	-	K081946	K071687
PRODUCT CODE	HQF	HQF	GEX
INTENDED USE	Photocoagulation of ocular tissue including the retina and pigmented tissue	Photocoagulation of ocular tissue including the retina and pigmented tissue	Photocoagulation of ocular tissue including the retina and pigmented tissue
INDICATIONS FOR USE	The Vitra 810 is intended for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following: • Retinal photocoagulation for the treatment of: o Diabetic retinopathy including: ▪ Nonproliferative retinopathy ▪ Macular edema ▪ Proliferative retinopathy o Retinal Tears, Detachments and Holes o Lattice degeneration o Age-related macular degeneration (AMD) with choroidal neovascularization (CNV) o Retinopathy of prematurity o Sub-retinal (choroidal) neovascularization o Central and Branch Retinal Vein	810 nm Indications for Use: The Supra Twin Ophthalmic Laser Photocoagulator wavelength 810nm is indicated for use: Photocoagulation or ablation of pigmented tissue within the eye, Transscleral ciliary body ablation (treatment is reserved for patients with chronic glaucoma and those not responding to conventional treatments), Transpupillary photocoagulation, Endophotocoagulation, Treatment of complicated rhegmatogeous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumben patients), transpupillary photocoagulation of choroidal	The Iridex IQ 810 is intended for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following: • Retinal photocoagulation for the treatment of: o Diabetic retinopathy including: ▪ Nonproliferative retinopathy ▪ Macular edema ▪ Proliferative retinopathy o Retinal Tears, Detachments and Holes o Lattice degeneration o Age-related macular degeneration (AMD) with choroidal neovascularization (CNV) o Retinopathy of prematurity o Sub-retinal (choroidal) neovascularization o Central and Branch Retinal Vein Occlusion

	Occlusion • Laser Trabeculoplasty, Iridotomy, Transscleral Cyclophotocoagulation for the treatment of glaucoma, including: o Primary open angle o Closed angle o Refractory Glaucoma (recalcitrant/uncontrolled)	neovasculature, and Age related macular degeneration (AMD) treaments.	• Laser Trabeculoplasty, Iridotomy, Transscleral Cyclophotocoagulation for the treatment of glaucoma, including: o Primary open angle o Closed angle • Refractory Glaucoma (recalcitrant/uncontrolled)
TYPE OF DELIVERY SYSTEM	Slit lamp Indirect ophthalmoscope Operating microscope Cyclophotocoagulation probes Laser probes	Slit lamp Indirect ophthalmoscope Operating microscope Endocular probe	Slit lamp Indirect ophthalmoscope Operating microscope Cyclophotocoagulation probes Laser probes
LASER SOURCE	Laser Diode	Laser Diode	Laser Diode
WAVELENGTH	810 nm	810 nm	810 nm
TREATMENT POWER	50-3000mW (depending upon delivery device)	50-3000mW (depending upon delivery device)	50-3000mW (depending upon delivery device)
LASER SAFETY CLASS	4/IV	4/IV	4/IV
PULSE DURATION	Continuous wave mode: 10 ms to continuous (up to 60 seconds) Subthreshold (Subliminal) mode (Ton): 0.1 ms to1.0 ms (5% to 35% duty cycle)	Continuous wave mode: 10 ms to 60 seconds Repeat mode: 0.1, 0.15, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7 & 1s	Continuous wave mode: 10 ms to continuous (up to 60 seconds) Subthreshold mode (Ton): 0.025 ms to1.0 ms (0.5% to 50% duty cycle) TTT mode: 10 seconds to 1800 seconds
REPEAT INTERVAL	Continuous wave mode: 50 ms to 1000 ms and one pulse Subthreshold (Subliminal) mode (Toff): 0.3 ms to 19 ms (duty cycle: 5% to 35%)	Repeat mode: 0.1 – 1 s	Continuous wave mode: 50 ms to 1000 ms and one pulse Subthreshold mode (Toff): 1.0 ms to 9.5 ms (duty cycle: 0.5% to 50%)
AIMING BEAM SOURCE	Red Laser Diode, 1 mW maximum	Red Laser Diode, 1 mW maximum	Red Laser Diode, 1 mW maximum
AIMING BEAM WAVELENGTH	635 – 650 nm	635-650 nm	635 – 650 nm
SIZE	18 (H) x 19.5 (W) x 30 (D) cm 7.1” (H) x 7.7” (W) x 11.8” (D)	14.6 cm High x 33 cm Wide x 30.7cm	-

WEIGHT	5.6 kg / 12.3lbs	9.5 kg / 21 lbs.	-
COOLING	By Peltier effect	By Peltier effect	Air cooled
POWER REQUIREMENT	250 VA	240 V	-

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 major level of concern was provided.

Conclusions

The Vitra 810 and the primary predicate device, the Quantel Medical Supra Twin, supported by the Iridex IQ810 secondary predicate device have the same intended use and similar technological characteristics and are therefore substantially equivalent.