May 12, 2022

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

Re: K220430
Trade/Device Name: Capsulo
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: March 11, 2022
Received: March 14, 2022

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 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,

Anjana Jain, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220430

Device Name
CAPSULO

Indications for Use *(Describe)*
CAPSULO is indicated for photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.

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

Quantel Medical
CAPSULO
K220430

510(k) Owner
Quantel Medical
1 rue Bois Joli
CS40015
63808 Cournon D'Auvergne-Cedex
France

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

Date Prepared: May 9, 2022

Trade Name of Device
CAPSULO

Common or Usual Name
Ophthalmic laser

Classification Name
Ophthalmic Laser; 21 C.F.R. §886.4390
Class II
Product Code: HQF

Predicate Device(s)
Quantel Medical Optimis Fusion YAG cleared in K140336

Device Description
The Yttrium Aluminum Garnet (YAG) ophthalmic laser system produces short pulses of focused infrared light at a wavelength of 1,064 nm. These pulses can be precisely positioned using a slit lamp microscope and a dual-point aiming system. The energy contained in a short pulse is concentrated by focusing a very small spot (10 um) so that the formation of plasma is at the focal point. The firing causes an acoustic wave that radiates from the focal point and breaks the near tissue which is known as disruptive photo-effect.

Once formed, plasma absorbs and further diffuses incident light, protecting deeper structures. Furthermore, the divergence of the beam after the focal point protects the retina from damage that could otherwise occur by the absorption of concentrated energy in the Nd:YAG treatment beam.

As the treatment energy is increased, the size of the plasma formed also increases, until a larger and stronger acoustic wave is produced. For increased energy, it is necessary to focus the treatment beam further behind the ocular structure being treated.

The Nd:YAG 1064 nm laser operates at a nano-second pulse rate and the laser energy is delivered to the treatment site using the integrated slit lamp.

Indications for Use
CAPSULO is indicated for photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.

Substantial Equivalence
Quantel Medical believes that the CAPSULO is substantially equivalent to a legally marketed predicate device that is a Class II medical device which is the Quantel Medical Optimis Fusion cleared in K140336. The intended use of the CAPSULO is the same as the intended use of YAG mode of the predicate device and the indications for use are also identical to the YAG mode. Both devices are prescription devices for use by trained healthcare providers. Table 1 provides a comparison of the CAPSULO to the predicate device.

Table 1
CAPSULO Substantial Equivalence

GENERAL SPECIFICATIONS			
Manufacturer	**QUANTEL MEDICAL**	**QUANTEL MEDICAL**	**Comparison**
Model	CAPSULO	OPTIMIS FUSION (YAG treatment mode)	-
510 (K) Number	K220430	K140336	-
Intended Use	Treatment of ocular pathology	Treatment of ocular pathology	Substantially equivalent
Indications for Use	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy	Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy	Substantially equivalent

Clearance Type	Prescription	Prescription	Substantially equivalent
User	Healthcare Professional	Healthcare Professional	Substantially equivalent
TREATMENT LASERS			
Laser Energy Intensity	Selected by Physician	Selected by Physician	Substantially equivalent
Laser Energy source	Q-Switched, Nd: YAG	Q-Switched, Nd: YAG	Substantially equivalent
Laser Wavelength	1064 nm	1064 nm	Substantially equivalent
Pulse setting	1,2 and 3 pulses per shot, selectable	1,2 and 3 pulses per shot, selectable	Substantially equivalent
Energy Settings	0.3 – 10 mJ (in 1 pulse) 0.6-18 mJ (in 2 pulses) 0.9-25.5 mJ (in 3 pulses)	0.3–10 mJ (in 1 pulse) 0.6-18 mJ (in 2 pulses) 0.9-30 mJ (in 3 pulses)	Substantially equivalent
Repetition Rate (Max)	3 Hz single pulse 1.5 Hz double pulse 1.5 Hz triple pulse	2.0 Hz single pulse 1.5 Hz double pulse 1.5 Hz triple pulse	Substantially equivalent
Pulse Duration	4 nanoseconds	4 nanoseconds	Substantially equivalent
Spot Size in air	10 microns (84% energy in diameter) 8 microns FWHM	10 microns (84% energy in diameter) 8 microns FWHM	Substantially equivalent
Offset (in air)	0 to +/- 500µm	Variable +150µm;0;-150µm	Substantially equivalent.
AIMING LASERS			
Aiming Beam laser type	Green diode	Red diode	Substantially equivalent
Aiming Wavelength	515 nm	635±5 nm	Substantially equivalent

The CAPSULO has similar technological characteristics to the predicate device. Both devices are Q-Switched Nd: YAG lasers with a wavelength of 1064 nm. The pulse settings are identical and the energy settings are the same for 1 and 2 pulses and within the range of the predicate device for 3 pulses. The repetition rate is the same for double and triple pulses but for single pulses is 3 Hz for the CAPSULO compared to 2 Hz for the predicate device. This minor difference in repetition rate does not impact substantial equivalence. Other key laser settings are the same for the two devices with the exception of the offset (in air). The offset of the CAPSULO is 0 to $\pm$500 um compared to +150 um, 0, -150 um for the predicate device. This feature in the CAPSULO helps facilitate accurate positioning of the optical breakdown to avoid damage to the retina and lens. Both devices utilize a diode aiming laser and both devices are delivered via a slit lamp. Therefore, the CAPSULO is substantially equivalent to the Optimis Fusion predicate device.

Performance Data

Non-clinical testing was performed to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device.

- AAMI ANSI ES60601-1 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 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 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability
- IEC 60601-2-22 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
- ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5 : Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

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

Based on the intended use, technological characteristics, and performance testing, the subject device has been shown to be substantially equivalent to the predicate.