DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 25, 2017

Quantel Medical
c/o Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K170067
Trade/Device Name: Easyret
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: June 20, 2017
Received: June 22, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170067

Device Name
Easyret®

Indications for Use *(Describe)*

The Easyret® is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation, pan retinal photocoagulation for vascular and structural abnormalities of the retina and uvea including:

- Proliferative and severe nonproliferative diabetic retinopathy,
- Choroidal neovascularization
- Branch retinal vein occlusion
- Treatment of choroidal neovascularization associated with wet age-related macular degeneration
- Retinal tears and detachments,
- Certain forms of macular edema
-Retinopathy of Prematurity
- Iridotomy in angle closure glaucoma and trabeculoplasty in open angle glaucoma

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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*"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."*

# 510(k) SUMMARY

## Quantel Medical
## Easyret®

**510(k) Owner**

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**Submission Correspondent:**

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5 Timber Lane
North Reading, MA 01864
Phone: 978-207-1245

Date Prepared: July 19, 2017

**Trade Name of Device**

Easyret®

**Common or Usual Name**

Ophthalmic Laser

**Classification Name**

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

**Predicate Device**

Quantel Medical Supra Scan (K120825)

**Device Description**

Easyret® is an integrated photocoagulation laser system including a slit lamp and a single column table. It provides a yellow laser beam (577nm).

Easyret® laser is available with the following configurations:
- A single slit lamp delivery system:

With this model two different slit lamps manufactured by CSO (CSO SL 9800 5x and CSO SL 9900 5x) are available. These slit lamps models have been cleared under K992836.

- A slit lamp delivery system and a laser indirect ophthalmoscope (LIO) optional port

In addition to the slit lamp delivery system, an optional LIO (laser indirect ophthalmoscope) can be used with the laser. Quantel Medical recommends the use of the following LIO models: Heine Omega 500 and Keeler Vantage +.

The touch screen includes a user interface where laser treatment settings such as power, pulse duration, spot size treatment and aiming beam intensity level can be programmed.

The user interface allows the physician to quickly select and access the following 3 treatment modes:

- Monospot treatment: This selection allows the user to carry out thermal "traditional" laser treatment using single spot via 4 delivery modes: Single, Repeat, Painting or Continuous.

- MultiSpot treatment: The MultiSpot mode allows automatically consecutive several laser spots according a pattern selected and the treatment patterns are customizable: square, circle, triple arc and macular grid.

- SubLiminal treatment: The sequencing (SubLiminal mode, or sub-threshold) is used to split the energy delivery into several successive very short pulses (microseconds) separated by a cooling time (interval).

Feedback to the user, such as laser operating state, number of performed laser spots, etc. is provided through the user interface. The laser treatment can be initiated by pressing on a footswitch and aborted by releasing it.

**Intended Use / Indications for Use**

The Easyret® is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation, pan retinal photocoagulation for vascular and structural abnormalities of the retina and uvea including:

- Proliferative and severe nonproliferative diabetic retinopathy,
- Choroidal neovascularization
- Branch retinal vein occlusion
- Treatment of choroidal neovascularization associated with wet age-related macular degeneration
- Retinal tears and detachments,
- Certain forms of macular edema
- Retinopathy of Prematurity

- Iridotomy in angle closure glaucoma, and trabeculoplasty in open angle glaucoma

**Substantial Equivalence**

Easyret® is substantially equivalent to the Quantel Medical Supra Scan cleared in K120825. The indications for use statement for the Easyret® is exactly the same as the indications for use statement for the predicate device. Additionally, both of the devices are prescription devices which are intended to be used by trained medical personnel. The use of the different laser parameters of the Easyret® and the predicate device are under control of the physician for the different phases of the treatment. Therefore, the Easyret® has the same intended use as the identified predicate device and may be found to be substantially equivalent to the predicate device.

The Easyret® and the predicate device have the same technological characteristics. In the Easyret®, the delivery system allows movement of the laser beam with the scanner and to change the spot size with a zoom, is integrated inside the slit lamp whereas, in the predicate device, the delivery system is added to the slit lamp. The components (scanner and zoom) are the same in the Easyret® and the predicate device but in the Easyret® it is one unit that can not be separated from the slit lamp. The scanner and zoom are mechanically integrated into the slit lamp for a more compact design and they can not be used with another slit lamp. In the Easyret, the laser cavity is an integral part of the device while in the Supra Scan the laser must be connected to the slit lamp.

The predicate device and the Easyret® use the same laser wavelength of 577 nm. The Easyret® device has a fiber laser cavity compared to the predicate device that has an Optically Pumped Semiconductor Laser (OPSL) cavity. In the OPSL cavity, there are pump diodes, an infrared laser cavity that emits at 1154 nm and an Second Harmonic Generator (SHG) that generates the 577 nm laser beam. The infrared laser cavity is a solid state cavity meaning that there are free space beams that oscillate between mirrors. The SHG module that generate the 577 nm laser beam is integrated inside the Infrared laser cavity. In the fiber laser cavity, there are the same parts as the OPSL cavity: pump diodes, an infrared laser cavity that emits at 1154 nm and an SHG that generates the 577 nm laser beam. But the infrared laser cavity is in fiber optic and the SHG module is outside the infrared laser cavity. At the output, the 577 nm laser beam of the two devices have the same wavelength and same power (2W).

The two laser cavities are driven with the same electronics that allow the laser beam to be switched on and off with the same times, so the exposure times settings are the same. The range in the CW mode has been reduced from 0.007 – 60 s to 0.01 – 45 s because the 0.007 s and 60 s exposure times are not commonly used in clinical practice. In SubLiminal mode, the exposures times (Ton) are the same (0.1 to 1 ms) but the minimum interval time (Toff) is reduced to 0.3 ms compared to 1 ms in the predicate device. That allows higher duty cycles (9 to 25%) with an exposure time of 0.1 ms.

The spot size range of the Easyret® is 50 to 400 µm whereas the predicate device is 50 to 500 µm. The 500 µm spot size is not commonly used in clinical practice. The delivered

power, spot size and exposure time of the Easyret® can be adjusted in the same ranges as the predicate device resulting in the same range of fluence delivered to the treatment area.

After reviewing the differences between the two systems, the Easyret® is as safe and effective as the predicate device as they share equivalent features and have the same intended use.

**Performance Data**

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

- AAMI/ANSI ES60601-1:2005/(R)2012 + A1:2012, C1:2009(R)2012 and A2:2010/(R)2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007: 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 62366-1 Medical Devices-Part 1: Application of usability engineering to medical devices
- 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 2nd Edition Part 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.