

JUN 25 2014  
K140336

**510(k) Summary for the Quantel Medical**  
**Family of OPTIMIS FUSION Ophthalmic Laser Systems, (OPTIMIS FUSION SLT/YAG, OPTIMIS FUSION YAG, OPTIMIS FUSION SLT) and Delivery Device (Slit lamp adaptor) and Accessories**

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

**1. General Information**

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Summary Preparation Date: June 13, 2014

**2. Names**

Device Trade Name: Family of OPTMIS FUSION Ophthalmic Laser  
Systems, Delivery Device and Accessories  
OPTIMIS FUSION SLT/YAG  
OPTIMIS FUSION YAG  
OPTIMIS FUSION SLT

Common Name: Ophthalmic Laser

Classification Names: Laser Instrument, Surgical, Powered and Laser,  
Ophthalmic  
Product Code: HQF (21 CFR 886.4390)  
Panel: Ophthalmology

### **3. Predicate Device**

- Lumenis Family of Selecta Ophthalmic laser Systems, Delivery Device and Accessories : (K081704)
- Carl Zeiss Meditec VISULAS YAG III (K042139)
- Quantel Medical Solutis (K130933)

### **4. Device Description**

The QUANTEL MEDICAL OPTIMIS FUSION is an ophthalmic surgical laser designed for performing photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser including dissection of the posterior capsule of the eye (posterior capsulotomy), dissection of the pupillary membranes (pupillary membranectomy), and iridotomy/iridectomy; and selective laser Trabeculoplasty.

The Family of OPTIMIS FUSION Ophthalmic Lasers, Delivery Device and Accessories consists of the following models:

- 1) OPTIMIS FUSION YAG – a Nd: YAG Laser providing-switched laser pulses at a wavelength of 1064 nm for use in photodisruption of ocular tissue (posterior capsulotomy, pupillary membranectomy, iridotomy/iridectomy). The 1064 treatment beam delivers 4 ns, 0.3 -10mJ adjustable and selectable single, double or triple pulse of energy. It is conditioned through beam shaping optics to generate a photodisruption micro pulse of plasma at a precision adjustable location relative to the visual focal plane (located at slit lamp center of rotation) and along the slit lamp objective lens axis. A twin aiming beam is also focused by the slit lamp objective to a converging 10 µm spot located at the focal point of the lens. The focal point of photodisruption is adjustable 150µm in the posterior direction and -150µm in the anterior direction by the physician relative to this convergence of the twin aiming beams.
- 2) OPTIMIS FUSION SLT - a Nd: YAG Laser providing Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty. The treatment beams delivers a 4 nsec, 0.3-2mJ adjustable single pulse of energy. The aiming and treatment beams are coaxial with each other and focussed by the slit lamp objective to a 400µm spot at the focal point of the lens.
- 3) OPTIMIS FUSION YAG/SLT - a Nd: YAG Laser providing Q-switched laser pulses at a wavelength of 1064 nanometers for use in photodisruption or Q-switched frequency doubled pulses at a wavelength of 532 nm for use in Selective Laser Trabeculoplasty, depending upon the mode selected. The OPTIMIS FUSION YAG/SLT contains two aiming beam modules that produce a single beam for the 532nm mode and a dual beam for the 1064nm mode, respectively.

For each OPTIMIS FUSION model, the physician controls delivery of laser energy from the OPTIMIS FUSION control display unit and activates the treatment laser beam with a footswitch or joystick pushbutton. In addition, a laser slit lamp adaptor may be coupled to each of the above OPTIMIS FUSION models and connected to a currently cleared QUANTEL MEDICAL 532nm photocoagulator (VITRA (K04236), SUPRA (K07776), VITRA MULTISPOT (K122251)) to allow to the physician to use the *Slit Lamp Adaptor* to deliver 532 nm continuous wave laser energy for retinal photocoagulation.

The OPTIMIS FUSION produces short, individual pulses of focused laser light with wavelengths of either 1064 nm or 532 nm, depending on the selected operational mode. Using a slit lamp microscope and aiming beam, the pulsed light is accurately targeted on a structure within the patient's eye.

When the photodisruptor mode is selected, the treatment wavelength is 1064nm. A twin-aiming beam targets the area of tissue disruption. The energy contained within a single short pulse is concentrated by focusing to a very small spot size so that plasma formation occurs at the focal point. This creates an acoustic wave which disrupts nearby tissue.

When the SLT mode is selected, the treatment wavelength is 532nm. A coaxial aiming beam targets the trabecular meshwork via a contact lens. The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork.

## **5. Indications for Use**

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.
- OPTIMIS FUSION SLT: Selective Laser Trabeculoplasty
- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy; and Selective Laser Trabeculoplasty

## **6. Substantial Equivalence**

The indications for use statement for the OPTIMIS FUSION FAMILY is exactly the same as the indications for use statement for the Lumenis Family of

SELECTA Ophthalmic Laser Systems, Delivery Device and accessories (predicate device). Each of the families contains multiple configurations of the laser system with different indications for use statements. Both families include an SLT model, a YAG model and a model which combines the SLT and YAG. The indications for use statements for each version of the product are identical between the families. Additionally, the YAG model of the Optimis Fusion Family is also being compared to the Carl Zeiss Meditec VISULAS YAG III cleared in K042139. Both systems are cleared for performing posterior capsulotomy and peripheral iridotomy procedures while the Optimis Fusion YAG is also indicated for pupillary membranectomy. The SLT model of the Optimis Fusion Family is also being compared to the Quantel Medical Solutis cleared in K130933. Both systems are cleared for Selective Laser Trabeculoplasty (SLT).

The OPTIMIS FUSION FAMILY and the predicate devices have the same technological characteristics. The OPTIMUS FUSION FAMILY and the Lumenis SELECTA family each include multiple models within the family. Both the OPTIMUS FUSION FAMILY and the Lumenis SELECTA family include an SLT model, a YAG model and a model that combines the SLT and YAG lasers in one unit. The VISULAS YAG III only includes a YAG model and therefore, will only be compared to the YAG model of the Optimis Fusion. The Quantel Medical Solutis has only a SLT model and therefore, will only be compared to the SLT model of the Optimis Fusion.

The Optimis Fusion SLT is a Q-Switched frequency doubled Nd: YAG laser with a wavelength of 532 nm as are the Selecta SLT model and Solutis. The Optimis Fusion SLT, the Selecta SLT model and Solutis all operate in single pulse modes. The energy range for both devices is 0.3-2.0 mJ and the Solutis is 0.2-2.0 mJ. The spot size in air is 400 microns with a focus angle of < 3 degrees for all systems. The maximum energy density at minimum exposure is  $1.6 \text{ J/cm}^2$  for all three systems. The repetition rate for all three systems is 2.0 Hz, the pulse duration is 4 ns for the Optimis Fusion SLT and Solutis and is 3 ns for the Selecta SLT. The maximum average power is 4 mW for all three systems. The differences between the three systems are considered extremely minor in significance and don't affect the safety or efficacy of the devices.

The OPTIMIS FUSION YAG is a Q-Switched Nd: YAG laser with a wavelength of 1064 nm as is the Selecta 1064 model and the VISULAS YAG III. All of the devices are pulsed with single spot modes and all modes operate in user selectable bursts of 1, 2 or 3 pulses. The energy range for all devices is 0.3-10.0 mJ. The spot size in air is 10 microns with a focus angle of 16 degrees for all three systems.

The OPTIMIS FUSION YAG/SLT includes the features and specification of both the OPTIMIS FUSION SLT system and the OPTIMIS FUSION YAG system combined in one device. The specifications of each individual system remain

unchanged when they are combined into one unit. This is exactly the same as the Lumenis Selecta Duet which combines the Selecta SLT and Selecta 1064 features.

All of the systems use a 635 nm red diode for aiming. All of the systems use a slit lamp as the delivery system for the laser energy. The Optimis Fusion models use the CSO SL980 slit lamp previously cleared by FDA in K992836.

Therefore, the OPTIMIS FUSION FAMILY is substantially equivalent to the predicate devices.

## **7. Performance Data**

Laboratory testing was conducted to validate and verify that the Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories met all design specifications and was substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

June 25, 2014

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

Re: K140336

Trade/Device Name: Optimis Fusion: SLT, YAG and YAG/SLT  
Regulation Number: 21 CFR 886.4390  
Regulation Name: Ophthalmic Laser  
Regulatory Class: Class II  
Product Codes: HQF  
Dated: May 16, 2014  
Received: May 19, 2014

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. 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 Small Manufacturers, International and Consumer Assistance 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” (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

**Kesia Y. Alexander -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

**Indications for Use**

510(k) Number (if known): K140336

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**Indications for Use:**

- OPTIMIS FUSION YAG: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy.
  
- OPTIMIS FUSION SLT: Selective laser Trabeculoplasty
  
- OPTIMIS FUSION YAG/SLT: photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy ; and Selective laser Trabeculoplasty

Prescription Use X AND/OR Over The Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles Chiang -S  
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