FEB - 7 2005

510(k) SUMMARY K043236

This 510(k) summary of safety and effectiveness for the modification in the Indications for Use for the Vitra Ophthalmic Laser Photocoagulator is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Quantel Medical

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Preparation Date: November 2004
(of the Summary)

Device Name: Quantel Vitra Ophthalmic Laser Photocoagulator

Common Name: Ophthalmic Laser, frequency doubled Nd:YAG (532 nm) laser
Laser Surgical Instrument, frequency doubled Nd:YAG (532 nm) laser

Classification Name: Ophthalmic laser (see 21 CFR 886.4390)

Product Code: HQF; Panel: 86

Predicate devices: B.V.I. Viridis Laser (K960867); Novus Verdi Laser and Delivery Systems (K991258), Carl Zeiss Visulas 532s (K013402), and the 532 nm laser of the Quantel Viridis Twin Laser (K023464).

Device description: The Quantel Vitra Ophthalmic Laser Photocoagulator is a Nd:YAG frequency doubled laser with a KTP crystal which emits a beam of coherent light at 532 nm. The energy is delivered to the treatment site(s) via delivery systems/devices.

Indications: The Vitra Ophthalmic Laser Photocoagulator is indicated for retinal photocoagulation in the following conditions:

With an indirect ophthalmoscope – for peripheral photocoagulation for the treatment of proliferative diabetic retinopathy and retinal detachments.

With an endocular probe – for intraocular retinal photocoagulation as an adjunct to vitrectomy surgery (and not the sole indication for vitrectomy) in the management of complicated rhegmatogenous and tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy.

With a slit Lamp – for the treatment of proliferative diabetic retinopathy, choroidal neovascularization secondary to age-related macular degeneration, and retinal detachments.

Performance Data: None required.

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the Vitra Ophthalmic Laser Photocoagulator is substantially equivalent to the cited legally marketed predicates. Information regarding delivery systems which may be used with the laser is supplied by Quantel Medical; the individual devices or systems are marketed by their respective manufacturers who have the responsibility for complying with applicable regulations and marketing requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2005

Quantel Medical
c/o Mr Roger Barnes
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K043236
Trade/Device Name: Quantel Vitra Ophthalmic Laser Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF
Dated: November 19, 2004
Received: November 22, 2004

Dear Mr. Barnes:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043236

Device Name: Quantel Vitra Ophthalmic Laser Photocoagulator

Indications for Use Statement:

The Vitra Ophthalmic Laser Photocoagulator is indicated for retinal photocoagulation in the following conditions:

With an indirect ophthalmoscope – for peripheral photocoagulation for the treatment of proliferative diabetic retinopathy and retinal detachments.

With an endocular probe – for intraocular retinal photocoagulation as an adjunct to vitrectomy surgery (and not the sole indication for vitrectomy) in the management of complicated rhegmatogenous and tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy.

With a slit Lamp – for the treatment of proliferative diabetic retinopathy, choroidal neovascularization secondary to age-related macular degeneration, and retinal detachments.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043236