4.0 510(K) SUMMARY

K 103056

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

FEB - 1 2011

4.1 SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

a. Applicant:
Carl Zeiss Meditec AG
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7740 Jena
Germany

b. Contact Person:
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c. Date Summary Prepared: December 21, 2010

4.2 DEVICE NAME, CLASSIFICATION AND ESTABLISHMENT REGISTRATION

a. Trade/Proprietary Name: VISULAS Trion Laser System with the *VITE* option

b. Common/Usual Name: Ophthalmic surgical laser

c. Classification Name: Laser instrument, surgical, powered

d. Classification Code(s): GEX, 21 CFR §878.4810

e. Reviewing Panel: General and Plastic Surgery Devices

f. Establishment Registration #: 9615030

4.3 PREDICATE DEVICE INFORMATION

PREDICATE DEVICE	MANUFACTURER	510(K) CLEARANCE NUMBER	CLEARANCE DATE
VISULAS Trion Laser System	Carl Zeiss Meditec	K072514	September 21, 2007
VISULAS 532s Laser System with the *VITE* option	Carl Zeiss Meditec	K100035	March 17, 2010
PASCAL Photocoagulator	OptiMedica Corporation	K043486, K081744, K091666, K092621	March 3, 2005, September 9, 2008, July 15, 2009, September 25, 2009

4.4 DEVICE DESCRIPTION

The VISULAS Trion Laser System with the *VITE* option is a multi-wavelength ophthalmic surgical laser intended for use in the photocoagulation of ocular tissues in treatment of diseases of the eye.

Similar to the predicate device, the VISULAS Trion Laser System (K072514) laser, energy for the proposed device is delivered via transpupillary delivery or intraocular endoprobe delivery.

The VISULAS Trion Laser System with the *VITE* option includes a modified laser slit lamp (LSL) that features a multi-spot treatment cascade delivery option. The modified LSL is identical to the LSL offered with the predicate device, the VISULAS 532s Laser System with the *VITE* option (K100035), also manufactured by Carl Zeiss Meditec.

4.5 STATEMENT OF INTENDED USE

The VISULAS Trion Laser System is intended for use in single-spot laser photocoagulation of ocular tissues for the treatment of diseases of the eye, such as:

- Photocoagulation of the retina
- Trabeculoplasty for treatment of glaucoma
- Iridotomy for treatment of glaucoma.

The VISULAS Trion Laser System with the *VITE* option is intended for use in multi-spot retinal, panretinal, focal and grid photocoagulation of ocular tissues in the treatment of diseases of the eye including:

- Proliferative and nonproliferative diabetic retinopathy
- Macular edema
- Branch and central retinal vein occlusion
- Lattice degeneration
- Retinal tears and detachments
- Choroidal neovascularization associated with wet age-related macular degeneration.

4.6 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The VISULAS Trion Laser System with the *VITE* option has the same operating characteristics and is substantially equivalent to the predicate VISULAS Trion Laser System (K072514), also manufactured by Carl Zeiss Meditec AG. Both the predicate and proposed devices deliver laser energy via a Laser Slit Lamp (LSL), the Laser Indirect Ophthalmoscope LIO Trion (for transpupillary delivery) or the endoprobe (for intraocular delivery).

Substantial equivalence is also drawn to the previously cleared VISULAS 532s Laser System with the *VITE* option (K100035) which incorporates the same Laser Slit Lamp (LSL) that offers the same multi-spot treatment cascade functionality as the proposed device. The Pascal Photocoagulator (K043486, K081744, K091666, K092621) achieves similar multi-spot delivery in the same manner as both the proposed and predicate VISULAS Trion and VISULAS 532s with VITE option devices (K072514 and K100035).

4.7 BRIEF SUMMARY OF NONCLINICAL TESTS & RESULTS

The VISULAS Trion Laser System with *VITE* option has been designed and tested to applicable standards including software, functionality, electrical and electromagnetic compatibility. The determination of substantial equivalence is based on the comparison between the results of performance data conducted using the VISULAS Trion with the *VITE* option and the predicate devices. These results demonstrate the ability of the proposed device to produce photocoagulation of ocular tissues that is comparable to the photocoagulation produced by the predicate devices.

4.8 CONCLUSION

The VISULAS Trion Laser System with the *VITE* option is substantially equivalent to the predicate devices, the Laser Systems VISULAS Trion (K072514), VISULAS 532s with option *VITE* (K100035) and the Pascal Photocoagulator (K043486, K081744, K091666, K092621).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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FEB - 1 2011

Re: K103056
Trade/Device Name: VISULAS Trion Laser System with the *VITE* Option
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: December 31, 2010
Received: January 03, 2011

Dear Ms. Brimacombe:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103056

Device Name(s): VISULAS Trion Laser System with the *VITE* option

Indications for Use:

The VISULAS Trion Laser System is intended for use in single-spot laser photocoagulation of ocular tissues for the treatment of diseases of the eye, such as:

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- Lattice degeneration
- Retinal tears and detachments
- Choroidal neovascularization associated with wet age-related macular degeneration.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103056