FEB 2 2 2001

ZEISS

510(k) Summary

K003995

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. Submitter's Name:
   Carl Zeiss, Inc.
   One Zeiss Drive
   Thornwood, NY 10594
   (914) 681 7880
   Contact Person: Scott A. Margolin,
   December 1, 2000

2. Trade Name: Visulas YAG II$^{plus}$ Ophthalmic Laser
   Classification Name: Laser; Neodymium: YAG, ophthalmic for Posterior Capsulotomy
   21 CFR § 886.4392: Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.

3. We are claiming substantial equivalence to the Q-Switched Nd: YAG laser by Ellex Laser Systems (K992824), as both are Nd: YAG lasers for ophthalmic applications and share the same indications for use; and also to the Carl Zeiss Visulas YAG II Laser (K926452), to include indication for use for peripheral iridotomy based upon a change to 21 CFR 886.4392.

4. The Visulas YAG II$^{plus}$ is a Neodymium: Yttrium: Aluminum: Garnet (Nd:YAG) laser for ophthalmic applications. The Zeiss Visulas Nd:YAG laser, which is substantially similar to the VISULAS YAG II. The original classification for this regulation was "Nd:YAG laser for posterior capsulotomy". On February 11, 2000, FDA issued a Final Rule amending the classification and codification for 21 CFR 886.4392 to (Volume 65, Number 29 Page 6893-6894) for Nd: YAG laser for peripheral Iridotomy from Class III to Class II. 21 CFR 886.4392 was therefore amended to "Nd: YAG Laser for posterior capsulotomy and Peripheral Iridotomy".

   The VISULAS YAG II$^{plus}$ is designed for use in ophthalmic applications, including posterior capsulotomy and can also be used for peripheral iridotomy. The VISULAS YAG II$^{plus}$ operates in the 1064 nm wavelength. The beam diameter in focus is 10 μm. The pulse length is less than 4 nanoseconds. The maximum energy output per pulse is 10 mJ (millijoules). The number of pulses per burst (repetition rate) is 3 pulses. The total energy per single burst is 10 mJ; double burst is 23 mJ; and triple burst is 37mJ.

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5. This device will be used in ophthalmic applications, in particular as a posterior capsulotomy and peripheral iridotomy in the same manner as the Ellex Systems predicate device.

6. The Carl Zeiss VISULAS YAG II*plus* and the predicate devices are substantially equivalent because they have the same intended use and / or share virtually the same design. The reason for this filing rests primarily in the change of indications permitted by regulation. These devices present the same questions regarding safety and effectiveness. Any differences between the two devices do not effect the safety or effectiveness of the device. Their basic functionality and intended use are virtually the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2001

Mr. Scott A. Margolin
Regulatory Affairs Specialist
Carl Zeiss, Inc
One Zeiss Drive
Thornwood, New York 10594

Re: K003885
Trade Name: Visulas YAG II$^{plus}$
Regulatory Class: II
Product Code: GEX
Dated: December 1, 2000
Received: December 15, 2000

Dear Mr. Margolin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost
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**

**Carl Zeiss, Inc.**
**VISULAS YAG II*plus***
**510(K) Submission**

510(K) Number : K003885

Device Name : VISULAS YAG II*plus*

Indications for Use :

This device will be used in ophthalmic applications, including posterior capsulotomy and peripheral iridotomy. This device is intended for use primarily by physicians and health care workers and may only be used under the supervision of a physician. This device will not be sold to the general public.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003885

Prescription Use ✓
(Per 21 CFR 801.109)