JAN 29 1999

K983868

510(k) Summary

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. Submitter's Name:
Carl Zeiss, Inc.
1 Zeiss Drive
Thornwood, NY 10594
(914) 681 7880
Contact Person: Scott A. Margolin
October 27, 1998

2. Trade Name: OPMI® TwinER Surgical Microscope
Classification Name: Surgical Microscope: § 878.4700
Instrument, Surgical Powered, Laser: § 878.4810

3. We are claiming substantial equivalence to the Sharplan Laser, Inc.'s 1041s (K900077) and the Premier Centauri Laser System (K933841) predicate devices, which already have pre-market clearance.

4. The OPMI® TwinER Surgical Microscope is a surgical microscope with an integrated solid-state Er:YAG (Erbium Yttrium aluminum garnet) laser. The Er:YAG laser is used for the ablation of biological tissue. The OPMI® TwinER is designed for use in general surgery where coagulation is not required, and otology, rhinology, and laryngology ("ENT") applications. Because the Er:YAG laser operates in the 2,940 nm wavelength and is absorbed very well by water, it causes minimal damage to the peripheral tissues from thermal absorption. This makes the Er:YAG particularly effective in traditional and microsurgery in the ear.

   The therapy beam is a Class IV laser with adjustable power output between 10 mJ and 100 mJ. The OPMI® TwinER also uses an aiming beam to position the therapy beam, which operates in the 660-680 nm wavelength. The aiming beam is a Class IIIA laser with adjustable power output between 0.2 mW and 3 mW.

   The therapy and aiming beams are delivered to the surgical field via a micromanipulator. A mirror, which can be finely adjusted using a joystick, allows the exact positioning of the laser beam.

5. This device will be used in general surgical applications where coagulation is not required and in surgical ENT applications, in particular as a surgical otology laser, in the same manner as the Sharplan 1041s predicate device (with the exception that the Sharplan device may be used where coagulation is required).

The OPMI® TwinER is intended for use in the following applications: general surgery which does not require coagulation; general surgical ENT, microsurgery on the middle ear; stepedoplasty; for preparation of sites for osteosynthesis; microsurgery on ossicles, tympanic membrane, ablative surgery on soft tissues (for example: ligament severance of the stapes muscle); and for the removal of exostosis.

6. The Zeiss OPMI® TwinER and the predicate devices are substantially equivalent because they all utilize a laser to perform tissue ablation. The OPMI® TwinER and the Sharplan 1041s (K900077) both achieve the surgical effect of tissue ablation in ENT/ otology applications by laser energy. Although the type of laser employed by the OPMI® TwinER differs from that used by the Sharplan 1041s, their basic functionality and intended use are virtually the same. These devices present the same questions regarding safety and effectiveness. Any differences between the two devices do not affect the safety or effectiveness of the device.

Similarly, the OPMI® TwinER and the Premier Centauri Laser (K933841) both achieve the effect of hard tissue ablation through the application of Er: YAG lasers. Although the Centauri laser is intended for dental applications rather than surgical otology, both devices utilize the Er: YAG laser on similar tissue types. The basic functionality of these two devices is virtually the same. The technological characteristics of the two devices pose the same types of questions regarding safety and effectiveness. Any differences between the two devices do not affect the safety or effectiveness of the device.

Numerous studies have proven that the Er:YAG laser, such as that used by the OPMI® TwinER, is safe and effective. Studies indicate that the Er:YAG laser is in fact safer and more effective than CO_2 lasers for certain ENT applications. The CO_2 laser operates at a wavelength of 10,600 nm (10.6 μm), achieving tissue ablation through a thermal effect, which may result in thermal damage to the delicate surrounding tissues. The Er:YAG, however, operates at a wavelength of 2,940 nm (2.94 μm), which is nearly the maximum absorption rate for light in water. The laser energy is entirely absorbed by the water in the tissue and converted to thermal energy. This leads to a rapid increase in water temperature and then to evaporation, followed immediately by a microexplosion. Thus, tissue ablation is achieved in a more mechanical fashion, rather than through the thermal effect of the CO_2 lasers. By this mechanism, the Er:YAG laser ablates without inducing significant thermal effects to the surrounding tissues and fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1999

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

Re: K983868
Trade Name: OPMI® TwinER Surgical Microscope
Regulatory Class II:
Product Code: GEX
Dated: October 27, 1998
Received: November 2, 1998

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,

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

Enclosure

JAN 29 1999

INDICATIONS

Carl Zeiss, Inc.
OPMI® TwinER 510(K) Submission

510(K) Number : K983868

Device Name : OPMI® TwinER Surgical Microscope

Indications for Use :

This device will be used in the same manner as all: (a) surgical microscopes are used and (b) as all lasers are used in ENT and general surgery not requiring photocoagulation. The device is primarily intended to allow surgeons to perform tissue ablation with minimal peripheral thermal effects. More specifically, the device can be used for: general surgery which does not require photocoagulation; and in ENT applications, including microsurgery in the middle ear, stapedoplasty, for preparation of sites for osteosynthesis, microsurgery on ossicles, tympanic membrane, ablative surgery on soft tissues (for example: ligament severance of the stapes muscle), and removal of exostosis.

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.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983868

Prescription Use
(Per 21 CFR 801.109)

Over-The-Counter Use
(Per 21 CFR 801.109)

Carl Zeiss, Inc.
One Zeiss Drive
Thornwood, NY 10594

(914) 747-1800
Fax (914) 682-8296
www.zeiss.com