K072823

510(k) Summary for the MERILAS 532α Ophthalmic Surgical Laser

Name and Address of Sponsor and Manufacturer

MERIDIAN AG
Bierigutstrasse 7
Thun 3608
Switzerland
Phone +41 33 334 11 11
Fax +41 33 334 11 19

DEC 14 2007

Establishment Registration Number

8030988

Name and Address of Official Correspondent

Regulatory Insight, Inc.
13 Red Fox Lane
Littleton, Colorado 80127
Contact: Mr. Kevin Walls, RAC
Telephone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

Device Name

Trade Name: MERILAS 532α
Common Name: Ophthalmic laser
Classification Name: Ophthalmic laser

Classification, Panel and Product Code

Class II, Ophthalmic, HQF

Indications for Use

The MERILAS 532a is indicated for use in retinal photocoagulation, iridotomy and laser trabeculoplasty.

Device Description

The methods for delivery of the laser treatment beam to the desired tissue in the eye are:

- Slit lamp delivery device (also identified as: slit lamp adapter) such as the SLA-BMBQ
- Laser indirect ophthalmoscope
- Endo fiber

The delivery method can be altered by exchanging the appropriate delivery device and connecting it to the base laser unit. The Autokey connector which belongs to each delivery device ensures that the base laser unit always gets the necessary information about the attached delivery device. The required delivery device has to be connected to the base laser unit before turning on the base laser unit.

During the start up procedure the MERILAS 532α identifies the attached delivery device and internally sets the appropriate parameters. The MERILAS 532α laser itself has built in sensors which do not allow the laser to fire if the delivery device fitted is not suitable in anyway.

For better viewing of the status of the laser unit when space is limited the display unit including the input devices can be removed from the base laser unit and placed on a more convenient space where good access as well as good viewing is possible. The maximum distance the display unit can be placed away from the base laser unit is 1 m due to maximum cable length.

After adjusting the desired parameters on the display of the base laser unit the treatment mode can be selected. In the treatment mode the red aiming beam (635 nm), generated by a laser diode, gets started and indicates the user to which area the treatment beam will be released. The physician selects the target tissue by aiming the red aiming beam to the desired tissue before releasing the treatment pulse.

The treatment laser is a diode pumped Nd:YVO laser which gets frequency doubled by using a KTP crystal. It is radiating at 532 nm. The transmission of the laser light gets achieved by focusing the laser light into an optical fiber and transmitting it to the delivery device. Laser power up to 2.5 W can be delivered out of the fiber. The laser delivery time can be adjusted from 10 ms up to 5 s.

The system can be operated from a 90-260 VAC, 50/60Hz single-phase power outlet. The mechanics of the MERILAS 532α is build out of anodized aluminium, painted sheet metal, and copper.

The optional slit lamp adapter SLA-BMBQ guides the laser beam from the laser unit into the illumination set of a slit lamp and focuses to the desired treatment area. The diameter of the spot can be adjusted in a range from 50 µm to 5 mm by turning the dial wheel at the slit lamp adapter.

The mechanics of the SLA-BMBQ is build out of anodized aluminium.

Substantial Equivalence

The MERILAS 532α is substantially equivalent to the following legally marketed device, which has been granted marketing clearance by FDA:

Carl Zeiss VISULAS 532s (510(k) # K013402)

A side-by-side comparison between the Carl Zeiss VISULAS 532s and the MERILAS 532α is provided below.

Side-by-side comparison:

Area/Parameter	Predicate Device VISULAS 532s (K013402)	New device MERILAS 532α
Laser type	Frequency doubled Nd:YVO	Frequency doubled Nd:YVO
Pumping	Diode	Diode
Wavelength	532 nm	532 nm
Cooling	Air	Air
Max. power	1500 mW	2500 mW
Aiming beam	620 - 650 nm	625 - 655 nm
Delivery	Slit lamp adapter Endo fiber Laser indirect ophthalmoscope Laser slit lamp	Slit lamp adapter Endo fiber Laser indirect ophthalmoscope
Power requirements	400 W	250 W
Voltage requirements	90 - 264 VAC	90 - 260 VAC
Weight	15 kg	7 kg
Indications for use	The VISULAS 532s laser is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye. The laser energy is delivered via either transpupillary delivery or intraocular endroprobe delivery	The MERILAS 532a is indicated for use in retinal photocoagulation, iridotomy and laser trabeculoplasty.
Design	Base Laser unit with detachable display unit and delivery device options.	Base Laser unit with detachable display unit and delivery device options.
Controls	Controls on the base laser unit and on the detachable display unit.	Controls on the base laser unit and on the detachable display unit.
Display	Parameter monitoring and selection on display panel.	Parameter monitoring and selection on display panel.
Hardware	µP-based system control touch sensitive display unit	µP-based system control touch sensitive display unit
Anatomical sites	Eye	Eye
Where used	Hospitals, clinics, consulting rooms	Hospitals, clinics, consulting rooms
Slit lamp adapter	VISULINK 532	SLA-BMBQ

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Meridian AG
c/o Kevin Walls, Principle Consultant
Regulatory Insight, Inc
13 Red Fox Lane
Littleton, CO 80127

Re: K072823
Trade/Device Name: MERILAS 532α Ophthalmic Surgical Laser
Regulation Number: 21 CFR 886. 4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: November 21, 2007
Received: November 23, 2007

Dear Mr. Walls:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

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): K072823

Device Name: MERILAS 532α

Indications for Use: The MERILAS 532a is indicated for use in retinal photocoagulation, iridotomy and laser trabeculoplasty.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/11/2007

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K072823