K091064

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 27 2009

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	OD-OS GmbH Warthestr. 21 14513 Teltow Germany Phone: +49 3328 312 82-100 Fax: +49 3328 312 82-999
OFFICIAL CORRESPONDENT:	Judy F. Gordon, D.V.M. Regulatory Consultant to OD-OS GmbH 733 Bolsana Drive Laguna Beach, CA 92563 Tel: (949) 715-0609 Fax: (949) 715-0610 judy@clinregconsulting.com
DATE PREPARED:	April 10, 2009
TRADE NAME:	NAVILAS Laser System
COMMON NAME:	Retinal Photocoagulator with a Digital Fundus Camera
DEVICE CLASSIFICATION:	Laser Instrument, Surgical, Powered (Class II, per 21 CFR §878.4810 Camera, Ophthalmic Class II, per 21 CFR §886.1120 Device, Storage, Images, Ophthalmic Class I per 21 CFR §892.2010 Device, Communication, Images, Ophthalmic Class I per 21 CFR §892.2020
PRODUCT CODES:	GEX; HKI, NFF, NFG

SUBSTANTIAL EQUIVALENCE

The NAVILAS Laser System is substantially equivalent to the following devices listed in Table 1.

TABLE 1
PREDICATE DEVICES FOR THE NAVILAS LASER SYSTEM

510(K) #	TRADE NAME	MANUFACTURER
Laser Photocoagulation		
K072823	MERILAS 532nm Laser	Meridian AG
K043486	Pascal Photocoagulator	Optimedica Corporation
Retinal Imaging		
K053044	OPTO Global Digital Fundus Camera System	OPTO Global, Inc.
K052268	VISUCAM PR NM Digital Camera	Carl Zeiss Meditec AG
K011877	FF450 Plus VISUPAC System	Carl Zeiss Jena GmbH

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The NAVILAS Laser System is a retinal laser photocoagulator with an integrated digital fundus camera. The NAVILAS Laser System combines imaging technologies (fundus live imaging, infra-red imaging and fluorescein angiography) with established retinal laser photocoagulation treatment methods by providing the doctor a system for imaging and treatment planning prior to the photocoagulation.

The NAVILAS Laser System is comprised of a laser photocoagulation module, digital imaging camera, computer hardware, and a software platform intended to be used to capture display, store and manipulate images captured by the fundus camera.

Like the predicate devices, laser photocoagulation with the NAVILAS is performed using single shot (Single Spot Mode), repeated shots (Repeat Mode), and scanned patterns (Pattern Mode). All treatment-related information and images are continuously displayed on the monitor to provide the physician an optimal platform for the photocoagulation procedure.

INDICATION FOR USE

The NAVILAS is indicated for use in retinal photocoagulation, as well as for the imaging (capture, display, storage and manipulation) of the retina of the eye, including via color, fluorescein angiography and red-free imaging; and for aiding in the diagnosis and treatment of ocular pathology in the posterior segments of the eye.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The NAVILAS Laser System has the same intended use, indications, and very similar principles of operation as for the cleared predicate devices, the MERILAS 532nm Laser System (K072823) and the Optimedica Pascal Photocoagulator (K043486) for laser photocoagulation. Imaging functionalities are similar to those of the OPTO Digital Fundus Camera (K053044), the Visucam PR NM Digital Camera (K052268), and the FF450 Visupac System (K011877), which are also indicated for use for the capture, display and storage of digital images of the retina and fundus. The minor differences between the NAVILAS Laser System and the listed predicate devices do not raise any new questions of safety or of effectiveness in comparison to the predicate devices.

PERFORMANCE DATA

Performance verification and validation testing was completed to demonstrate that the device performance complies with specifications and requirements identified for the NAVILAS Laser System. This was accomplished by software and hardware verification & validation testing, along with system level bench testing of the NAVILAS Laser System. All criteria for this testing were met and results demonstrate that laser photocoagulation performed with the NAVILAS Laser System meets all performance specifications and requirements.

CONCLUSIONS

As described in this 510(k) Summary, all testing deemed necessary was conducted on the NAVILAS Laser System to ensure that the device is safe and effective for its intended use and is substantially equivalent to legally marketed devices intended for laser photocoagulation and retinal imaging to aid in the diagnosis and treatment of diseases of the eye.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

ClinReg Consulting Services, Inc.
c/o Judy F. Gordon, D.V.M.
Regulatory Consultant to OD-OS
733 Bolsana Dr.
Laguna Beach, CA 92651

OCT 2 7 2009

Re: K091064
Trade/Device Name: NAVILAS Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: HQF
Dated: October 14, 2009
Received: October 16, 2009

Dear Ms. Gordon:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091064

510(k) Number (if known): K091064

Device Name: NAVILAS Laser System

Indications for Use:

The NAVILAS Laser System is a retinal photocoagulator integrated with a digital fundus camera. The NAVILAS is indicated for use in retinal photocoagulation, as well as for the imaging (capture, display, storage and manipulation) of the retina of the eye, including via color, fluorescein angiography and infra-red imaging; and for aiding in the diagnosis and treatment of ocular pathology in the posterior segments of the eye.

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)

Bruce Drum

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

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