DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 2, 2015

OD-OS GMBH
c/o Judy F. Gordon
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K141851
Trade/Device Name: Navilas Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: HGF, GEX, HKI, NFF, NFG
Dated: November 29, 2014
Received: December 1, 2014

Dear Dr. 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. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Deborah L. Falls -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141851

Device Name
Navilas Laser System

Indications for Use *(Describe)*
The Navilas Laser System/Navilas Laser System 532+/ Navilas Laser System 577+ are indicated for use:

• In Retinal Photocoagulation for the treatment of Clinically Significant Diabetic Macular Edema (Focal or Grid Laser), Proliferative Diabetic Retinopathy (Panretinal Photocoagulation), Sub-retinal (Choroidal) Neovascularization (Focal Laser), Central and Branch Retinal Vein Occlusion (Scatter Laser Photocoagulation, Focal or Grid Laser), Lattice Degeneration, Retinal Tears and Detachments (Laser Retinopexy).

• For the imaging (capture, display, storage and manipulation) of the retina of the eye, including via color, fluorescein angiography and infrared imaging; and for aiding in the diagnosis and treatment of ocular pathology in the posterior segment of the eye.

• In Laser Trabeculoplasty for Primary Open Angle Glaucoma, as well as Iridotomy and Iridoplasty for Closed Angle Glaucoma.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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4.0 510(K) SUMMARY

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

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

APPLICANT:
OD-OS GmbH
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Germany

CONTACT PERSON:
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DATE SUMMARY PREPARED: December 22, 2014

4.2 NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

COMMON NAME: Photocoagulator with a Digital 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

TRADE/PROPRIETARY NAME: Navilas® Laser System

4.3 PREDICATE DEVICES

PREDICATE DEVICES FOR NAVILAS LASER SYSTEM

510(K) #	TRADE NAME	MANUFACTURER
K091064	Navilas Laser System	OD-OS
K123542	PASCAL® Synthesis Ophthalmic Scanning Laser System	Topcon Medical Systems
K071687	Iridex IQ Family	Iridex

PREDICATE DEVICES FOR NAVILAS LASER SYSTEM 532+

510(K) #	TRADE NAME	MANUFACTURER
K091064	Navilas Laser System	OD-OS
K123542	PASCAL® Synthesis Ophthalmic Scanning Laser System	Topcon Medical Systems
K071687	Iridex IQ Family	Iridex

PREDICATE DEVICES FOR NAVILAS LASER SYSTEM 577+

510(K) #	TRADE NAME	MANUFACTURER
K091064	Navilas Laser System	OD-OS
K123542	PASCAL® Synthesis Ophthalmic Scanning Laser System	Topcon Medical Systems
K071687	Iridex IQ Family	Iridex
K091581	Quantel Supra 577	Quantel

4.4 DEVICE DESCRIPTION

The NAVILAS Laser System combines imaging technologies (fundus live imaging, infra-red imaging and fluorescein angiography) with established retinal laser photocoagulation treatment methods, providing the doctor with a system for image capture, display, storage and manipulation for treatment planning and documentation.

The primary components of the Navilas Laser System include:

- One of three optional ophthalmic laser sources:
  - a frequency doubled ND:YVO_4 laser source that operates at 532nm, *or*
  - an optically-pumped semiconductor laser source that also operates at the same 532nm, *or*
  - an optically-pumped semiconductor laser source that operates at 577nm

- An integrated delivery system that directs the laser beam through ophthalmoscope optics using motorized mirrors,

- A digital camera and computer hardware that provides continuous real-time imaging using slit illumination that is projected through the ophthalmoscope optics and panned automatically at a rapid rate of 25 Hz across the subject area using the motorized mirrors. Imaging can be in color (using white light illumination) or in monochrome (using infrared illumination or blue light illuminations).

Laser photocoagulation with the NAVILAS can be performed using single shot (Single Spot Mode), repeated shots (Repeat Mode), and scanned patterns (Pattern Mode).

4.5 STATEMENT OF INTENDED USE

The Navilas Laser System/Navilas Laser System 532+/ Navilas Laser System 577+ are indicated for use:

- In Retinal Photocoagulation for the treatment of Clinically Significant Diabetic Macular Edema (Focal or Grid Laser), Proliferative Diabetic Retinopathy (Panretinal Photocoagulation), Sub-retinal (Choroidal) Neovascularization (Focal Laser), Central and Branch Retinal Vein Occlusion (Scatter Laser Photocoagulation, Focal or Grid Laser), Lattice Degeneration, Retinal Tears and Detachments (Laser Retinopexy).
- For the imaging (capture, display, storage and manipulation) of the retina of the eye, including via color, fluorescein angiography and infrared imaging; and for aiding in the diagnosis and treatment of ocular pathology in the posterior segment of the eye.
- In Laser Trabeculoplasty for Primary Open Angle Glaucoma, as well as Iridotomy and Iridoplasty for Closed Angle Glaucoma.

4.6 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The Navilas Laser System has the same indications for use, similar design and functional features and is therefore substantially equivalent to the predicate devices.

4.7 PERFORMANCE STANDARDS

The Navilas is designed, manufactured and tested in accordance with both mandatory and voluntary standards including:

- IEC 60601-1 Medical Electric Equipment, Part 1: General requirements for safety
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for safety (Collateral standard: electromagnetic compatibility – requirements and tests)

- IEC 60601-2-22 — Medical Electrical Equipment, Part 2: Particular requirements for the safety and diagnostic and therapeutic laser equipment
- IEC 62366 — Medical Devices – Application of usability engineering to medical devices
- IEC 60825-1 — Safety of Laser Products, Part 1: Equipment classification and requirements
- ISO 15004-2 — Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
- ISO 14971 — Application of risk management to medical devices

This device also complies with European Medical Device Directive 93/42/EEC and U.S. Federal Performance Standards per 21 CFR Part 1040 for light emitting products.

4.8 SUMMARY OF PERFORMANCE TEST RESULTS

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 the Navilas Laser System meets all performance specifications and requirements.

4.9 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 treatment and imaging of the eye.