DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 22, 2016

Judy Gordon, D. V. M.
Regulatory Affairs Consultant
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K162191
Trade/Device Name: Navilas® Laser System 577s
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: GEX, HKI, NFF, NFG
Dated: October 17, 2016
Received: October 18, 2016

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" (21 CFR 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,

Kesia Alexander

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)*
K162191

Device Name
Navilas® Laser System 577s

Indications for Use *(Describe)*

The Navilas Laser System 577s is 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 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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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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.

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DATE PREPARED: October 17, 2016

TRADE NAME: Navilas® Laser System 577s

COMMON NAME: 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 577s is substantially equivalent to the Navilas Laser System 577+ cleared under K141851. This laser model is functionally identical to the predicate Navilas laser, the same scientific technology as well as same intended use, with the exception of the elimination of the fluorescein angiography imaging capability of the predicate laser system. This model will also include hardware design improvements for manufacturability, including:

- A new graphical user interface monitor and display format
- Relocation of the scanner controls to inside the optical head and conversion from motorized to manual base height adjustment
- Designation of table as an optional accessory
- Inclusion of a combination objective element that can be used with commercially available macular, peripheral and gonioscopic contact lenses

As with the predicate device, the Navilas Laser 577s is intended to aid in the diagnosis and treatment of ocular pathology of the eye.

DESCRIPTION OF THE DEVICE

The Navilas Laser 577s is a laser photocoagulator with an integrated digital fundus camera. The Navilas 577s Laser System combines imaging technologies (fundus live imaging, and infra-red imaging) with established laser photocoagulation treatment methods by providing the doctor a system for imaging and treatment planning prior to the photocoagulation.

The Navilas Laser 577s is comprised of:

- A semiconductor laser source that operates at 577nm. The semiconductor laser source for the Navilas 577s is identical to the laser source used with the Navilas 577+ cleared under K141851.
- An integrated delivery system that directs the laser beam through an ophthalmoscope using motorized mirrors.
- A digital camera that provides continuous real-time imaging in color with white light illumination of the fundus, or in monochrome using infrared illumination.
- A software platform intended to be used to capture display, store and manipulate images captured by the fundus camera.

The Navilas Laser System 577s supports the user during multiple steps of a laser treatment procedure with digital imaging, image storage, planning and laser treatment options including:

Digital imaging as provided by a color image with white light, supporting mydratic and non-mydratic image acquisition (with and without dilated pupils), or a monochrome IR image. Images are presented using a digital display. An illumination mode is selected where images are acquired and either stored or discarded after viewing on the touch sensitive digital display.

Image Storage - Captured images can be digitally stored in the Navilas Laser System 577s database along with other patient related data to create a complete patient record for future reference. Images from other devices may also be imported and stored.

Planning - Areas identified on acquired or imported images by the user that are selected for future treatment consideration can be marked through the use of treatment planning tools available. The physician has the ability to highlight areas on acquired images (called Points of Interest). These locations are created and manipulated using the touch sensitive digital display.

Laser Treatment - Treatment options are also unchanged from the predicate device with Single Pulse Mode, Repeat Mode and Scanned Pattern Mode available on all Navilas laser models. Pre-positioning of the aiming beam onto locations which are selected by the physician during planning is also facilitated. The position of the aiming beam can be monitored on the real-time image that is displayed on the touch sensitive digital display.

Report generation - Information collected in the database includes images obtained before, during and after treatment. This information may be used for the generation of patient reports for documentation purposes.

The Navilas Laser 577s can emit a 577 nm wavelength beam for photocoagulation with power up to 2000 milliwatt and pulse duration up to 4000 milliseconds. More characteristics of the device are given in the table for substantial equivalence below. The software platform is based on an embedded Windows operating system.

INDICATION FOR USE

The Navilas 577s Laser System is 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 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.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The technological characteristics of the Navilas Laser 577s are substantially equivalent to those of the predicate device as presented in the following table.

COMPARISON OF THE NAVILAS LASER PHOTOCOAGULATION TECHNOLOGY TO THE PREDICATE DEVICE

FEATURES AND CHARACTERISTICS	OD-OS NAVILAS LASER SYSTEM 577S (PROPOSED)	OD-OS NAVILAS LASER SYSTEM 577+ (K141851)	COMPARISON
Field of Use	**Ophthalmology**	**Ophthalmology**	**Same**
Laser Type	Retinal photocoagulating laser	Retinal photocoagulating laser	Same
Indications for Use	The Navilas 577s is 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 and infrared imaging; and for aiding in the diagnosis and treatment of ocular pathology in the posterior segment of the eye.	The Navilas 577+ is 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	No, the fluorescein angiography functionality is not offered with the proposed laser model

FEATURES AND CHARACTERISTICS	OD-OS NAVILAS LASER SYSTEM 577S (PROPOSED)	OD-OS NAVILAS LASER SYSTEM 577+ (K141851)	COMPARISON
	• In Laser Trabeculoplasty for Primary Open Angle Glaucoma, as well as Iridotomy and Iridoplasty for Closed Angle Glaucoma.	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.	
Laser medium	Optically pumped semiconductor laser source operating at 577 nm	Optically pumped semiconductor laser source operating at 577 nm	Same
Wavelength(s)	577 nm yellow	577 nm yellow	Same
Laser Output	Continuous-wave	Continuous-wave	Same
Treatment Power	< 2000 mW	< 2000 mW	Same
Treatment Pulse Duration	10 ms – 4000 ms 0.050 to 0.500 ms	10 ms – 4000 ms 0.050 to 0.500 ms	Same
Repeat Mode	Yes	Yes	Same
Pulse Interval Time	160 ms – 4000 ms Short pulse: 0.050 to 2.000 ms	160 ms – 4000 ms Short pulse: 0.050 to 2.000 ms	Same
Retinal Spot size	50 µm – 500 µm	50 µm – 500 µm	Same
Laser Class	IV	IV	Same
Aiming Laser Type	Semiconductor laser visible red diode	Semiconductor laser visible red diode	Same
Wavelength	635 nm	635 nm	Same
Maximum Avg. Power	Adjustable to less than 1mW	Adjustable to less than 1mW	Same
Laser Class	II	II	Same
Power Supply	115/230 VAC	115/230 VAC	Same

FEATURES AND CHARACTERISTICS	OD-OS NAVILAS LASER SYSTEM 577S (PROPOSED)	OD-OS NAVILAS LASER SYSTEM 577+ (K141851)	COMPARISON
Visualization Principle	Scanning slit lamp	Scanning slit lamp	Same
Imaging Modes	• mydriatic color imaging • non-mydriatic color imaging	• mydriatic color imaging • non-mydriatic color imaging • fluorescein angiography	Modified The fluorescein angiography is not offered with the proposed laser model
Image Storage and Analysis	Yes	Yes	Same
Treatment Planning Tools	Image Overlay, Points of Interest, Documentation	Image Overlay, Points of Interest, Documentation	Same
Operating system	Windows 10 Embedded	Windows XP Embedded	Modified An upgraded version of Windows is offered with the proposed laser model

PERFORMANCE DATA

Performance verification and validation testing was completed to demonstrate that the device performance complies with specifications and requirements identified for the Navilas 577s Laser System. This was accomplished by software and hardware verification & validation testing, along with system level bench testing of the Navilas Laser 577s. Software was tested in accordance with the Level of Concern (LOC) for the Navilas system software which is considered to be "major." In accordance with *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/uc m089543.htm,* a Major LOC is defined as any device where a malfunction of the software of the device could result in a death or serious injury.

All necessary bench testing was conducted on the Navilas Laser System 577s to support a determination of substantial equivalence to the predicate devices. The tests performed include:

- Illumination Safety – ISO 15004-2 Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection
- IEC 62304 – Medical Device Software – Software Life Cycle Process
- Human Factors and Usability –
    - Medical devices – Part 1: Application of Usability Engineering to Medical Devices, IEC 62366
    - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, IEC 60601-1-6
- Laser Product Safety Testing –
    - Medical Electric Equipment, Part 1: General requirements for safety, IEC 60601-1
    - Medical Electrical Equipment – Part 1-2: General requirements for safety (Collateral standard: electromagnetic compatibility – requirements and tests), IEC 60601-1-2
    - Medical Electrical Equipment, Part 2: Particular requirements for the safety and diagnostic and therapeutic laser equipment, IEC 60601-2-22.
    - Safety of Laser Products, Part 1: Equipment classification and requirements, IEC 60825-1Laser Bench testing to verify spot and patter placement accuracy.
- Software Verification and Validation

All criteria for this testing were met and results demonstrate that laser photocoagulation performed with the Navilas Laser 577s meets all performance specifications and requirements.