



October 29, 2025

OD-OS GmbH
Camila Mundt Ilgenfritz
Head of Regulatory Affairs
Warthestr. 21
Teltow, 14513
Germany

Re: K251772
Trade/Device Name: Navilas Laser System 577sl (156691)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: September 19, 2025
Received: September 25, 2025

Dear Camila Mundt Ilgenfritz:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251772

Device Name
Navilas Laser System 577sl

Indications for Use (Describe)

The Navilas® Laser System is an ophthalmic laser integrated with a digital camera. The Navilas® Laser System is indicated for the treatment of ocular pathology in the anterior and posterior segment of the eye, with supporting imaging functions (capture, display, storage and annotation) of the retina of the eye via color and infrared imaging.

The Navilas® Laser System is intended for use in the posterior segment to perform Retinal Photocoagulation, Panretinal photocoagulation, focal photocoagulation or grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- Proliferative and non-proliferative diabetic retinopathy
- Macular edema
- Choroidal neovascularization associated with wet age-related macular degeneration
- Age-related macular degeneration
- Central and branch retinal vein occlusion
- Lattice degeneration
- Retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including:

- Iridotomy
- Iridoplasty
- Trabeculoplasty

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
K251772**1. Submitter Information**

510(k) Owner: OD-OS GmbH
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Contact Person: Camila Mundt Ilgenfritz
OD-OS GmbH
Head of Regulatory Affairs
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Phone: (+49) 3328 31282148

Date Prepared: October 29th, 2025

2. Device Name and Classification

Device Trade Name: Navilas Laser System 577sL

Common Name: Photocoagulator

Regulation Name: Ophthalmic Laser (21 CFR 886.4390)

Device Classification: Class II

Product Code(s): **HQF, Ophthalmic Laser (21 CFR §886.4390)**

3. Predicate Device(s)

- **Primary Predicate:** Iridex PASCAL (Iridex, K223132)
Product code: HQF
- **Predicate 2:** Navilas Laser System 577s (OD-OS GmbH, K162191)
Product code: GEX, HKI, NFF, NFG
- **Predicate 3:** Yellow Laser Photocoagulator System YLC-500 (Nidek, K170302)
Product code: HQF

4. Device Description

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

The Navilas Laser System 577sL is comprised of:

- A semiconductor laser source that operates at 577nm wavelength. The laser can operate with Continuous Wave (CW) or Micro-Second Pulsing (MSP).
- 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 that is based on an embedded Windows operating system, that controls the startup, use, calibration, monitoring, and shutdown of the system.

The Navilas Laser System 577sL supports the user during multiple steps of a laser treatment procedure with digital imaging, image storage, planning and laser treatment options including: Digital imaging - Provided by a color image with white light, supporting mydriatic and non-mydriatic 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, exported or discarded after viewing on the touch sensitive digital display.

Image Storage - Captured images can be digitally stored in the Navilas Laser System 577sL 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 Pre-planned and Ad-hoc Modes 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 can be used for the generation of patient reports for documentation purposes.

The Navilas Laser System 577sL can emit a 577 nm wavelength beam for photocoagulation with power up to 1700 mW and pulse duration up to 4000 ms.

5. Indications for Use

The Navilas® Laser System is an ophthalmic laser integrated with a digital camera. The Navilas® Laser System is indicated for the treatment of ocular pathology in the anterior and posterior segment of the eye, with supporting imaging functions (capture, display, storage and annotation) of the retina of the eye via color and infrared imaging.

The Navilas® Laser System is intended for use in the posterior segment to perform Retinal Photocoagulation, Panretinal photocoagulation, focal photocoagulation or grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- Proliferative and non-proliferative diabetic retinopathy
- Macular edema
- Choroidal neovascularization associated with wet age-related macular degeneration
- Age-related macular degeneration
- Central and branch retinal vein occlusion
- Lattice degeneration
- Retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including:

- Iridotomy
- Iridoplasty
- Trabeculoplasty

6. Comparison of Technological Characteristics with the Predicate Device(s)

The Navilas Laser System 577sL is an ophthalmic laser that performs both retinal photocoagulation and laser trabeculoplasty. The Navilas 577sL is a variation of the Navilas Laser System 577s (Predicate 2) which was 510(k)-cleared under K162191 and modified step- wise over the years with minor changes documented via notes to file.

The Navilas 577sL is functionally identical to the current version of Navilas 577s, with the exception that the Navilas 577sL has a modified power range, an updated indications for use statement, and a few software improvements, including:

- Addition of two patterns options on planning function: macula grid pattern and double-spot titration
- Addition of a multiple snapshot acquisition option: allows for capturing a series of multiple snapshots with progressively increasing illumination intensity levels
- The proprietary *.npt import/export file format has been updated to allow capture, of additional patient-related meta data to enhance planning and back-up capabilities
- Minor adjustments to user interface for workflow efficiency associated with the changes listed above

Although the Navilas Laser System 577sL and the predicate devices do not share all the same technological characteristics, these differences do not raise different types of questions of safety and effectiveness.

Characteristic	Subject Device Navilas Laser System 577sl (OD-OS) K251772	Primary Predicate Iridex PASCAL (Iridex) K223132	Predicate 2 Navilas Laser System 577s (OD-OS) K162191	Predicate 3 Yellow Laser Photocoagulator System YLC-500 (Nidek) K170302	Comparison of Subject Device to Predicate Devices
Device Classification	II	II	II	II	Same
Product Code	HQF	HQF	GEX HKI, NFF, NFG	HQF	Same to Primary Predicate and Predicate 3 NOTE: Navilas Laser System 577s (Predicate 2) was originally assigned product code GEX (powered laser surgical instrument), which is the code that was historically assigned to ophthalmic lasers. More recently, ophthalmic lasers are assigned to product code HQF (ophthalmic lasers), which is more specific.
Regulation Number	21 CFR 886.4390	21 CFR 886.4390	21 CFR 878.4810	21 CFR 886.4390	Same to Primary Predicate and Predicate 3 NOTE: For Predicate 2 see note above.

Characteristic	Subject Device Navilas Laser System 577sl (OD-OS) K251772	Primary Predicate Iridex PASCAL (Iridex) K223132	Predicate 2 Navilas Laser System 577s (OD-OS) K162191	Predicate 3 Yellow Laser Photocoagulator System YLC-500 (Nidek) K170302	Comparison of Subject Device to Predicate Devices
Indication for Use	<p>The Navilas® Laser System is an ophthalmic laser integrated with a digital camera. The Navilas® Laser System is indicated for the treatment of ocular pathology in the anterior and posterior segment of the eye, with supporting imaging functions (capture, display, storage and annotation) of the retina of the eye via color and infrared imaging..</p> <p>The Navilas® Laser System is intended for use in the posterior segment to perform Retinal Photocoagulation, Panretinal photocoagulation, focal photocoagulation or grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:</p> <ul style="list-style-type: none"> • Proliferative and non-proliferative diabetic retinopathy • Macular edema • Choroidal neovascularization associated with wet age-related macular degeneration • Age-related macular degeneration 	<p>Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.</p> <p>Intended for use in the posterior segment to perform retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:</p> <ul style="list-style-type: none"> • proliferative and non-proliferative diabetic retinopathy • macular edema • choroidal neovascularization associated with wet age-related macular degeneration • age-related macular degeneration • lattice degeneration • retinal tears and detachments <p>Intended for use in the treatment of ocular pathology in the anterior segment including:</p> <ul style="list-style-type: none"> • Iridotomy 	<p>The Navilas® Laser System is an ophthalmic laser integrated with a digital camera. The Navilas® Laser System is indicated for use:</p> <ul style="list-style-type: none"> • 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 	<p>The Yellow Laser Photocoagulator System YLC-500 is intended to be used in ophthalmic surgical procedures including retinal and macular photocoagulation, iridotomy and trabeculoplasty.</p> <p>The Yellow Laser Photocoagulator System YLC-500 is intended to work in conjunction with the following delivery units in ophthalmic photocoagulation procedures: NIDEK SL-1800, SL-1600, ZEISS SL 130, HAAG BQ900, HEINE OMEGA 500</p>	<p>Similar Navilas 577sl has two additional indications for use in comparison to Predicate 2, which are within scope of the Primary Predicate (non-proliferative diabetic retinopathy and age-related macular degeneration)</p>

Characteristic	Subject Device Navilas Laser System 577sl (OD-OS) K251772	Primary Predicate Iridex PASCAL (Iridex) K223132	Predicate 2 Navilas Laser System 577s (OD-OS) K162191	Predicate 3 Yellow Laser Photocoagulator System YLC-500 (Nidek) K170302	Comparison of Subject Device to Predicate Devices
	<ul style="list-style-type: none"> Central and branch retinal vein occlusion Lattice degeneration Retinal tears and detachments <p>Intended for use in the treatment of ocular pathology in the anterior segment including:</p> <ul style="list-style-type: none"> Iridotomy Iridoplasty Trabeculoplasty 	<ul style="list-style-type: none"> Trabeculoplasty 	<p>pathology in the posterior segment of the eye.</p> <ul style="list-style-type: none"> In Laser Trabeculoplasty for primary open angle glaucoma, as well as iridotomy and iridoplasty for closed angle glaucoma 		
Laser medium	Optically pumped semiconductor laser	Optically pumped semiconductor laser	Optically pumped semiconductor laser	Optically pumped semiconductor laser	Same
Wavelength(s)	577 nm	577 nm and 532 nm	577 nm	577 nm	Same
Laser Class	IV	IV	IV	IV	Same
Laser Output	<ul style="list-style-type: none"> - Continuous Wave - Microsecond pulsing (MSP) 	<ul style="list-style-type: none"> - Continuous Wave - Microsecond pulsing 	<ul style="list-style-type: none"> - Continuous Wave - Microsecond pulsing (MSP) 	- Continuous wave	Same as Predicate 1 and 2. Similar to Predicate 3, when taking into account the treatment power and pulse duration ranges.
Treatment Power	<1700mW	0 to 2000 mW	< 2000 mW	50 to 1500 mW	Similar, range between Predicates 1/2 and Predicate 3. Differences do not raise different types of questions of safety and effectiveness. Performance testing was performed to verify and validate this change.

Characteristic	Subject Device Navilas Laser System 577sl (OD-OS) K251772	Primary Predicate Iridex PASCAL (Iridex) K223132	Predicate 2 Navilas Laser System 577s (OD-OS) K162191	Predicate 3 Yellow Laser Photocoagulator System YLC-500 (Nidek) K170302	Comparison of Subject Device to Predicate Devices
Treatment Pulse Duration	CW: 10 – 4000 ms MSP: 0.05 – 0.5ms	CW: 5 – 1000ms MicroPulse: 0.05 – 1.0 ms	CW: 10 – 4000 ms MSP: 0.05 – 0.5 ms	Single spot: 10 – 3000ms Scan Mode: 10 – 50ms Auto M Mode : 10 – 3000ms	Same as Predicate 2 Similar to Primary Predicate and Predicate 3.
Repeat Mode	yes	yes	yes	Not publicly reported	Same
Pulse Interval Time	10 – 4000 ms Short pulse: 0.05 – 2.0 ms	125 – 1000ms Micropulse: 0.1 – 10.0 ms	10 – 4000 ms Short pulse: 0.05 – 2.0ms	5 – 1000 ms	Same as Predicate 2 Similar to Primary Predicate and Predicate 3.
Retinal Spot size	50 – 500 µm	50 – 300 µm	50 – 500 µm	Slit lamp delivery unit: 50 – 990 µm Scan slit lamp delivery unit: 50 – 500 µm, 100 – 500 µm in scan mode B.I.O. delivery: 212 to 664 µm	Same as Predicates 2 and 3. Similar to Primary Predicate.
Visualization Principle	Scanning slit lamp	Scanning Slit lamp	Scanning slit lamp	Slit lamp	Same
Patterns	Multiple patterns: - single spot - titration spots (single/double) - freeform pattern - macula grid - rectangle - circle - arc	Multiple patterns: - Single Spot - Titration spots - Array - Hexagon - Arc - Triple Arc - Wedge - Triple Ring - Line - Octants - Enhanced Octants - PSLT 3 Row	Multiple patterns: - single spot - titration spots (single) - freeform pattern - rectangle - circle - arc	Multiple patterns: - Single - Square - Equal Space - Line - Triangle - Curve - Triple Curve - Circle - Arc - Triple Arc - Arcade Grid - Rectangle	Similar to predicate devices. All devices offer multiple patterns. The Navilas 577SL includes two patterns that are not available in the predicate devices (double titration spots and a Macula Grid pattern), but this difference does not raise different types of questions of safety and effectiveness.

Characteristic	Subject Device Navilas Laser System 577sl (OD-OS) K251772	Primary Predicate Iridex PASCAL (Iridex) K223132	Predicate 2 Navilas Laser System 577s (OD-OS) K162191	Predicate 3 Yellow Laser Photocoagulator System YLC-500 (Nidek) K170302	Comparison of Subject Device to Predicate Devices
					Software testing was completed to verify and validate these new patterns.
Aiming Laser Type	Semiconductor diode laser	Semiconductor diode laser	Semiconductor diode laser	Semiconductor diode laser	Same
Wavelength	635 nm	635 nm	635 nm	635 nm	Same
Maximum Avg. Power	Adjustable to less than 1mW	Adjustable to less than 1mW	Adjustable to less than 1mW	0.3±0.1 mW	Same
Laser Class	II	II	II	II	Same
Imaging Modes	- Color (non-mydratic and mydratic color) - Infra red	n/a	- Color (non-mydratic and mydratic color) - Infra red	n/a	Same as Predicate 2
Image Acquisition, Storage and Annotation	Yes	n/a	Yes	n/a	Same as Predicate 2, with additional option for multiple snapshots series
Treatment Planning Tools	Image Overlay, Points of Interest, Documentation	Documentation	Image Overlay, Points of Interest, Documentation	Documentation	Same as Predicate 2. Similar to Primary Predicate and Predicate 3.
Import/export function	Yes, shared folder on local network or USB	yes, export on USB	yes, shared folder on local network or USB	yes, export on local network or USB	Same as Predicate 2 with additional data now included on the proprietary npt file, e.g. multiple snapshots series

7. Summary of Non-Clinical Testing

Based on the risk assessment and design control requirements, the following verification and validation testing was performed:

- Optical radiation hazard evaluation and safety testing was conducted per:
 - ANSI Z80.36:2021 American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
- Electromagnetic compatibility (EMC) was conducted per:
 - IEC 60601-1-2:2020 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- Human factors testing was conducted per:
 - FDA guidance, “Applying Human Factors and Usability Engineering to Medical Devices”
 - ANSI/AAMI IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices, and
 - IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA Guidance for the Content of Premarket Submissions for Software Device Software Functions, June 2023, requiring Enhanced Documentation Level.
- Device performance bench testing

The device also complies with:

- Laser safety:
 - IEC 60601-2-22: 2007 (3rd Ed.) Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
 - IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements
- Electrical safety:
 - IEC 60601-1:2020 Medical electrical equipment – Part 1: General requirements for safety 1: collateral standard: Safety Requirements for Medical Electrical Systems.

Results of the non-clinical testing support a substantial equivalence determination. The Navilas Laser System 577sL is substantially equivalent to its predicate devices for the indications for use.

Clinical testing was not required for this product change.

8. Conclusions

The Navilas Laser System 577SL has the same intended use as the legally marketed predicate device(s) identified in this premarket notification. Some of the technological characteristics of the Navilas Laser System 577SL differ from those of the predicate device(s), but the differences do not raise new or different types of questions of safety or effectiveness.

The results of the non-clinical performance testing demonstrate that the Navilas Laser System 577SL functions as intended and meets all product design requirements and applicable standards. The non-clinical performance testing demonstrates that the Navilas Laser System 577SL meets all performance specifications and requirements and is substantially equivalent to the predicate devices, and is safe and effective.