March 18, 2026

Carl Zeiss Vision GmbH
℅ Jahmal Cannon
Regulatory Affairs Manager
Carl Zeiss Vision, Inc.
1040 Worldwide Blvd.
Hebron, Kentucky 41048

Re: K253834
Trade/Device Name: VISUREF 600
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: February 9, 2026
Received: February 9, 2026

Dear Jahmal Cannon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Alexander Beylin -S Date: 2026.03.18 17:08:02 -04'00'

for CAPT Bradley Cunningham, MSE, RAC
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253834

Device Name
VISUREF 600

Indications for Use *(Describe)*
VISUREF 600 is a combined autorefractor and keratometer.

The device supports the following measurements in eye examination of the anterior eye segment:

• Assessment of the opacity of the lens via retro-illumination.

• Measurement of tear film break-up time by recording the time between the last complete blink and the first appearance of dark spots in the fluorescein-infilled tear film.

• Imaging of the meibomian glands located in the upper and lower eyelids using infrared illumination.

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
Date prepared : 2026-03-16

Trade name: VISUREF 600
Common name: Combined autorefractor and keratometer
Classification name: AC-powered slitlamp biomicroscope (21 CFR 886.1850)
Predicate device: SL 220, ZEISS Meditec AG, submission number K162684

Device description

VISUREF 600 is an autorefraction and keratometry device. It can measure the objective refraction of the human eye, including sphere, cylinder, axis and higher order aberrations and the keratometry, including the central and peripheral corneal curvature.
Additional features are available to complement main use cases of the eye examination device.
Those features include:
- Visual acuity test including variations of contrast and glare
- Color image observation with optional use of color filters
- Opacity observation
- Meibomian gland assessment
- Measurement of tear film breakup time
- Measurement of pupil and white-to-white diameter

The main components are:
- Chinrest to support patient fixation
- Measurement unit including light emitting diodes and sensors for measurement as well as target images for the patient to look at
- User interface display and joystick to control the device operation
- Printer to print out measurement results

Intended Use

VISUREF 600 is intended to be used to measure the refractive power, corneal radii (Keratometry) and to assist in pre- and post-examination of the human eye.

Indications for Use

VISUREF 600 is a combined autorefractor and keratometer.
The device supports the following measurements in eye examination of the anterior eye segment:

- Assessment of the opacity of the lens via retro-illumination.
- Measurement of tear film break-up time by recording the time between the last complete blink and the first appearance of dark spots in the fluorescein-infilled tear film.
- Imaging of the meibomian glands located in the upper and lower eyelids using infrared illumination.

The indications for use of the subject device are within the intended use of the predicate device which is visualization of the anterior eye segment and do not raise any new questions of safety and effectiveness.

Classification

These VISUREF 600 functions correspond to the product code HJO in device class 2 and are subject of this premarket notification: Assessment of lens opacity and meibomian glands, tear film break-up time measurement.

Table 1: Technological Characteristics VISUREF 600

Illumination source	**Input**	**Exposure**
White LED	3.8V, 30mA	Continuous wave
Blue LED	3.8V, 30mA	Continuous wave
Peripheral LED	3.8V, 20mA	Continuous wave
Refraction LED	2.5V, 30mA	Repetitive pulsed
Chart LED	3.8V, 30mA	Continuous wave
Glare LED	3.8V, 30mA	Continuous wave
Meibography LED	1.7V, 100mA	Continuous wave
Mirering LED	3.8V, 60mA	Continuous wave

Technical Specifications		
Input	100–240 V AC, max. 1.0 – 0.6 A, 50–60 Hz	
Max. consumption	150 VA	
Mains fuse	T 3.15 A, 250 V	
Light hazard protection	Group 2 device acc. to ANSI 80.36-2021	
Laser class	I acc. to 21CFR 1040.10 and IEC 60825-1:2014	
Laser wavelength	850 nm	
Reported wavelength	555 nm	
Monitor	10.1" LCD 1280x800 Resistive Touch panel	
Overall dimensions (L x W x H)	[cm]	53 x 30 x 50, max. 53 x 34 x 50
Weight	[kg]	23
Chinrest travel distance (up and down)	[mm]	60 ± 3
Auto travel distance Up and down Left and right Front and back	[mm]	 ± 15 (± 3) ± 5 (± 2) ± 5 (± 2)
Automatic tracking scope Up and down Left and right Front and back	[mm]	 ± 5 ± 5 ± 5

Refraction Measurement	
Method	Hartmann-Shack
Number of measurement points	Up to 289
Measurement range of spherical aberration (at a vertex distance of 12 mm)	-20 D to +20 D
Measurement range for cylindrical and axial refraction	-12 D to +12 D 0° to 180° (increments of 1°)
Measurement accuracy	-10 to +10: ± 0.25 < -10 or > +10: ± 0.5
Display increments	0.01 / 0.12 / 0.25 D
Keratometer	
Corneal radius	5 ~ 13 mm Increment 0.01 mm
Corneal refraction (at corneal RI = 1.3375)	25.96 ~ 67.5 D
Corneal astigmatism	0 ~ 15 dpt
Accuracy K	± 0.05 mm

Summary of technological differences and similarities between subject and predicate device

SL 220 and VISUREF 600 both enable a visual examination of the anterior eye segment.

Within the substantially equivalent Indications for Use, the main technological difference between the subject and predicate devices is the method of visualization.

The predicate device SL 220 has an observation unit with the option of connecting a camera with a secondary screen to the eyepiece system, while the subject device VISUREF 600 uses the combination of a high-resolution camera and display.

The design of both devices ensures generating sufficient visual quality for the operator to accurately assess the patient's anterior eye segment. In conclusion, this technical difference does not raise any new questions of safety and effectiveness and does not adversely affect safety and effectiveness of VISUREF 600.

SL 220 and VISUREF 600 share the same fundamental operating principle to examine the same endpoints with only the wavelength of the light different due to the technology of the devices.
Both devices use LED illumination to visualize the patient's eye structures, thus enabling observation of lens opacification, tear-film break-up time and the meibomian gland.

Both devices perform direct illumination and retro-illumination as common examination techniques.

Both predicate and subject device were tested for light emission and conform to Group 2 limits acc. to ISO 15004-2:2007 and ANSI Z80.36-2021, respectively. Testing demonstrates that the devices operate within equivalent parameters concerning light emission and meet the same safety threshold.

Table 2: Substantial Equivalence Comparison

Parameters	**Subject device** **VISUREF 600** **Carl Zeiss Vision GmbH**	**Predicate device** **SL 220** **Carl Zeiss Meditec AG**	**Comparison**
Intended Use and Indications for Use	VR600 is intended to be used to measure the refractive power, corneal radii (Keratometry) and to assist in pre-and post-examination of the human eye. VISUREF 600 is a combined autorefractor and keratometer. The device supports the following measurements in eye examination of the anterior eye segment: ▪ Assessment of the opacity of the lens via retro-illumination. ▪ Measurement of tear film break-up time by recording the time between the last complete blink and the first appearance of dark spots in the fluorescein-infilled tear film. ▪ Imaging of the meibomian glands located in the upper and lower eyelids using infrared illumination.	An AC-powered slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.	Substantially equivalent
Intended user	• Technicians, Nurses • Ophthalmologists, Opticians, Optometrists or assistants • Biomed / Service technicians	• Ophthalmologist • Optometrist • Optician • Service technician • Cleaning personnel • Application expert/sales representative	Substantially equivalent

Parameters	**Subject device** **VISUREF 600** **Carl Zeiss Vision GmbH**	**Predicate device** **SL 220** **Carl Zeiss Meditec AG**	**Comparison**
Technological characteristics			
Power supply - Main	Mains voltage: 100 V – 240 V AC Mains frequency: 50 Hz – 60 Hz	Mains voltage: From 100V – 10% to 240 V +10% Mains frequency: 50/60 Hz	Substantially equivalent
Power consumption	Max. 150 VA	< 45 VA	Substantially equivalent
Visual representation	The user observes the human eye via a built-in camera with a screen integrated into the system.	The user observes the patient's eye structure through the observation unit with its stereomicroscope, tube and eyepiece. In addition, it is possible to view image data generated by digital cameras through the stereomicroscope at the graphical user interface.	Substantially equivalent
Illumination source	The VISUREF 600 illumination system uses LED to directly illuminate the patient's eye and visualize the eye structures. The user can control the brightness according to the lighting conditions.	The SL 220 illumination system uses LED to project a beam of light onto the patient's eye and directly illuminate the eye structures. The user can modify illumination and observation parameters including brightness.	Substantially equivalent
Prescription Use or Over-The-Counter Use	Rx only	Rx only	Substantially equivalent
Protection class acc. to IEC 60825	I	II	Substantially equivalent

Parameters	**Subject device** **VISUREF 600** **Carl Zeiss Vision GmbH**	**Predicate device** **SL 220** **Carl Zeiss Meditec AG**	**Comparison**
Light hazard protection	Group 2 acc. to ANSI Z80.36-2021	Group 2 acc. to ISO 15004-2:2007	Substantially equivalent
Principle of operation			
Measurement of tear film break-up time	The operator records the tear film break-up time using a manually controlled timer integrated into VISUREF 600.	The operator records the tear film break-up time using an external manually controlled timer.	Substantially equivalent
Assessment of the meibomian glands	Meibomian Gland assessment allows the operator to observe the morphological structure of the patient's meibomian gland. Standardized tables not included in VISUREF 600 can be used for comparison and evaluation after the examination.	Meibomian Gland assessment allows the operator to observe the morphological structure of the patient's meibomian gland. Standardized external tables can be used for comparison and evaluation after the examination.	Substantially equivalent
Assessment of the opacity of the lens	The operator can observe the opacification of the lens by assessing the black-and-white image displayed on the screen of VISUREF 600. After the examination this image can be compared to a standardized lens image grading system (Lens Opacities Classification System (LOCS) III).	The operator can observe the patient's lens opacification in the examination with SL 220 and afterwards determine the grade of cataract by comparing the image with the Lens Opacities Classification System (LOCS) III standard lens images.	Substantially equivalent

Brief summary of non-clinical testing and evidence

The results from design verification and validation confirm that the design and development outputs have met the design and development input requirements and that VISUREF 600 works as designed for the specified intended use.

VISUREF 600 software was designed, developed and released, and will be maintained in accordance with ANSI/ AAMI 62304:2006/A1:2016.

Software verification and validation testing was conducted, and documentation was provided as recommended for the required Basic Documentation Level.

VISUREF 600 has demonstrated in EMC and Electrical Safety Testing, and Performance Testing that it complies with the applicable safety and performance requirements according to the following standards:

ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
ANSI Z80.36-2021
IEC 60825-1:2014

VISUREF 600 was evaluated biocompatible according to ISO 10993-1:2018 with evaluations addressing cytotoxicity, sensitization, and irritation.

VISUREF 600 complies with the same standards and is as safe and effective as the predicate device SL 220. The generated evidence demonstrates substantial equivalence between the subject device and the predicate device.

Conclusion

VISUREF 600 is safe and effective and performs according to its intended use.

The subject device is similar in technological characteristics, performance, operating principle and indications for use, and is substantially equivalent to the predicate device SL 220 as concerns the relevant features. Technological differences between the subject device and the predicate device do not raise any new questions of safety and effectiveness and do not adversely affect safety and effectiveness of VISUREF 600.

Results of the non-clinical performance testing support the determination of substantial equivalence between the subject and predicate device for the proposed Indications for Use.

Therefore, VISUREF 600 meets the requirements for substantial equivalence as compared to the predicate device SL 220.