October 21, 2020

OCULUS Optikgerate GmbH
% Randy Prebula
Partner
Hogan Lovells, US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K201724
Trade/Device Name: Pentacam AXL Wave
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: MXK, HJO
Dated: September 18, 2020
Received: September 18, 2020

Dear Mr. Prebula:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201724

Device Name
Pentacam AXL Wave

Indications for Use *(Describe)*

The Pentacam AXL Wave is intended to image the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens. It is indicated for the evaluation of

- corneal shape,
- condition of the lens (opaque crystalline lens),
- the anterior chamber angle,
- anterior chamber depth,
- the volume of the anterior chamber,
- anterior or posterior cortical opacity,
- the location of cataracts using cross slit imaging with densitometry,
- corneal thickness,
- axial length,
- white-to-white distance,
- optical aberrations of the eye,
- and retroillumination imaging.

The Pentacam AXL Wave also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

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

OCULUS Pentacam AXL Wave

General Information

Applicant:

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Summary Prepared: October 20, 2020

Device Information

Classification Name:	Device, analysis, anterior segment (AC-powered slitlamp biomicroscope,)
Trade/Propriety Name:	Pentacam AXL Wave
Common Name:	Ophthalmic biomicroscope
Regulation Number:	21 C.F.R. § 886.1850
Device class:	II
Product Code:	MXK, HJO

Predicate Devices

Primary Predicate:	OCULUS Optikgeräte GmbH, Pentacam AXL (K152311)
Secondary Predicate:	LUNEAU SAS, VX120 (K143086)

Intended Use / Indications for Use

The Pentacam AXL Wave is intended to image the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens. It is indicated for the evaluation of

- corneal shape,
- condition of the lens (opaque crystalline lens),
- the anterior chamber angle,
- anterior chamber depth,
- the volume of the anterior chamber,
- anterior or posterior cortical opacity,
- the location of cataracts using cross slit imaging with densitometry,
- corneal thickness,
- axial length,
- white-to-white distance,
- optical aberrations of the eye,
- and retroillumination imaging.

The Pentacam AXL Wave also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

Product Description/Technological Characteristics

The Pentacam AXL Wave is intended to image the anterior segment of the eye to measure eye components, such as corneal thickness, anterior chamber depth, corneal curvature, corneal cylinder, corneal cylinder axis and white-to-white-distance. The axial length of the eye can be measured by a built-in interferometer. An also integrated aberrometer can determine the optical aberrations of the eye. By using retroillumination imaging, the back-lit eye can be observed.
The measured parameters can be used by physicians to calculate the power of the intraocular lens (IOL) implanted during a cataract surgery.

While rotating around the eye, the Pentacam AXL Wave captures Scheimpflug images of the anterior eye segment through varying axes. The Scheimpflug images created during an examination are transmitted to a connected PC.

Scheimpflug images can be captured within maximum of two seconds. Up to 138,000 genuine height values are measured and analyzed from the Scheimpflug images.

The Scheimpflug images are the basis for the height data which are used to calculate a mathematical 3D model of the anterior eye segment.

The mathematical 3D model, corrected for eye movements, provides the basis for all subsequent analysis.

The axial length of the eye is measured by interferometry. The aberrometry measurements are done by a common Hartmann-Shack-Aberrometer. The retroillumination works similar to the illumination method of slit-lamps.

New features in the device

The Pentacam AXL Wave combines the functions of the cleared Oculus Pentacam AXL device (K152311) with aberrometry measurements done by a common Hartmann-Shack-Aberrometer and retroillumination which works like the respective illumination method of slit-lamps. The new capabilities (aberrometry measurement and retroillumination imaging) are “add-ons” to the functionality of the Pentacam AXL that do not modify or impact the other capabilities in any way.

The Pentacam AXL Wave has functions subject to FDA premarket review as well as exempted functions that are not subject to FDA premarket review (“optical aberration of the eye” and “retroillumination imaging”). For these applications, FDA assessed those functions only to the extent that they could adversely impact the safety and effectiveness of the functions subject to FDA premarket review.

Performance Testing

EMC and electrical safety of the subject devices were evaluated using the following consensus standards**:** IEC 60601-1; IEC 60601-1-2.

Testing was also performed in accordance with ISO 15004-1, ISO 15004-2, ISO 22665 and IEC 60825-1 to demonstrate compliance with these standards.

Software verification and validation testing has also been performed.

Substantial Equivalence Discussion

As explained in detail below, the Pentacam AXL Wave is substantially equivalent to other legally marketed Scheimpflug imaging devices and optical aberrometers. Specifically, the Pentacam AXL Wave is substantially equivalent to the Pentacam AXL (K152311) and the Visionix VX120 (K143086).The Pentacam AXL Wave has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicates. A substantial equivalence chart comparing the similarities and differences between the Pentacam AXL Wave and its predicate devices is provided at the end of this section, below. As explained in more detail below, minor differences in the technological characteristics do not raise new questions of safety or efficacy. Bench and clinical testing demonstrate that the Pentacam AXL Wave is as safe and effective as its predicate devices.

Intended Use/ Indications for Use

The Pentacam AXL Wave has the same intended use as the predicate Pentacam AXL device, with the only difference being the addition of the ability to evaluate optical aberration of the eye and conduct retroillumination imaging. These additional functionalities are similar to the indications identified for the other predicate device, VX120.

The cleared Pentacam AXL and VX120 are also indicated to perform measurements and calculations. The Pentacam AXL Wave is further indicated for performing all these measurements in one device. The minor differences in the way that the indications are described do not alter the intended use of the device by creating a new intended therapeutic, diagnostic, prosthetic, or surgical

use of the device compared to the predicates. These measurements are substantially equivalent to the indications for the cleared Oculus Pentacam AXL device and LUNEAU VX120.

As described below, each of the measurements for the Pentacam AXL Wave device are performed individually and are substantially equivalent in terms of technology, safety and performance to two identified predicates. The subject Pentacam AXL Wave thus meets the first requirement for establishing substantial equivalence.

Technological Characteristics

The Pentacam AXL Wave combines the measurement capabilities of the cleared Oculus Pentacam AXL and the cleared VX120.

The combination of the two predicate devices' cleared technologies in one device does not impact the ability of either technology to operate per its separate intended use. As explained in more detail below, the Scheimpflug camera and optical interferometer of the Pentacam AXL Wave still operates in fundamentally the same manner as the Pentacam AXL and are not interfered with as a result of the additional functionalities.
Further, the Hartman-Shack aberrometer and retro-illuminator are fundamentally the same as the same features that are incorporated into the VX120. Because each technological component has already been used for the same purposes as used in the subject device, and the technological characteristics operate independently without interference from the other technological features, no new or different questions of safety or effectiveness are raised by the subject device.

The Pentacam AXL Wave and the VX120 both serve the function of wavefront aberrometer by using a Hartman-Shack aberrometer.

Both systems measure an optical wavefront using a wavefront sensor (Hartman-Shack sensor).

The Pentacam AXL Wave and the VX120 also serve the function of retroillumination by using illumination method of a slit-lamp biomicroscope.

The Pentacam AXL Wave also performs measurements of the corneal shape and cataracts, similarly to the cleared Pentacam AXL. Both the Pentacam AXL Wave and the Pentacam AXL use a digital camera with comparable resolution and the Scheimpflug principle to photograph the anterior segment of the eye and use the photographs to generate data and measurements about the eye.

Both devices also use IR LEDs for eye illumination, blue slit lamps with a slit slight of 14 mm as the light source for slit illumination, and a digital CMOS camera as the overview camera.

Minor differences, such as the spherical measurement range, which is reduces from -20D to +20D in the predicate device to -10D to +6D for the subject device, do not raise new questions of safety and effectiveness because the measurement range continues to be appropriate for the relevant patient group that is to be measured using the device.

The Pentacam AXL Wave and the Pentacam AXL use similar Pentacam software to display the measurements and three-dimensional displays. The software has been modified since the

clearance of the Pentacam AXL to display the additional measurements gained from the added wavefront aberrometer measurements and retro illumination.

Overall, the Pentacam AXL Wave has substantially equivalent technological characteristics to the predicate devices. The differences between the subject device and the cleared predicates are minor, and bench and clinical tests have confirmed the safety and effectiveness of the new device in achieving the indications for use.

Substantial Equivalence Table (Comparing the Tomographic and Biometer Technological Characteristics with the Relevant Predicate Device)

Device Type	**Subject device**	**Predicate device** (Scheimpflug imaging, axial length, etc.)
Model	Pentacam AXL Wave	Pentacam AXL
Manufacturer name	OCULUS Optikgeraete GmbH	OCULUS Optikgeraete GmbH
510(k) Number	TBD	K152311
	The Pentacam AXL Wave is intended to image the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens. It is indicated for the evaluation of • corneal shape, • condition of the lens (opaque crystalline lens), • the anterior chamber angle, • anterior chamber depth, • the volume of the anterior chamber, • anterior or posterior cortical opacity, • the location of cataracts using cross slit imaging with densitometry, • corneal thickness, • axial length, • white-to-white distance, • optical aberrations of the eye, • and retroillumination imaging. The Pentacam AXL Wave also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.	The Pentacam AXL is designed to take photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. To evaluate: - corneal shape, - analyze condition of the lens (opaque crystalline lens), - analyze the anterior chamber angle, - analyze anterior chamber depth, - analyze the volume of the anterior chamber, - analyze anterior or posterior cortical opacity, - analyze the location of cataracts (nuclear, sub capsular and or cortical), using cross slit imaging with densitometry, - corneal thickness, - axial length (by optical biometry), - white-to-white distance. The Pentacam AXL also performs calculations to assist physicians in determining the power of the intraocular lens for implantation
Scheimpflug Camera	Digital CMOS camera	Digital CCD camera
Resolution of Scheimpflug camera	1392x1040 pixel	1392x1040 pixel
Slit length	14 mm	14 mm
Slit width	35 µm	35 µm
Light source for slit illumination	Blue slit lamp (LED 470 nm)	Blue slit lamp (LED 470 nm)
Light source for eye illumination	4 IR LEDs (810 nm)	4 IR LEDs (810 nm)

Device Type	**Subject device**	**Predicate device** (Scheimpflug imaging, axial length, etc.)
Images	100 in 2 seconds	100 in 2 seconds
Rotation	360°	360°
Measuring points	up to 138,000	up to 138,000
Working distance	80 mm	80 mm
Physical principle	Scheimpflug principle / Optical interferometer	Scheimpflug principle / Optical interferometer
Calculation principle	Edge detection and 3D regression polynomial functions; detection of interference pattern and consideration of mirror position	Edge detection and 3D regression polynomial functions; detection of interference pattern and consideration of mirror position
Auto release function	Yes	Yes
Auto movement system	No	No
Fixation light	Yes, red LED (640 nm)	Yes, red LED (640 nm)
Overview camera	Digital CMOS camera	Digital CMOS camera
Resolution of overview camera	1280 x 960	640 x 480
Measurement range - Axial length	14 – 40 mm	14 – 40 mm
Light source for interferometer	IR Super luminescence diode (SLD)	IR Super luminescence diode (SLD)
Wavelength	880 nm	880 nm
SLD-Power for measurement	0.7 mW	0.84 mW
SLD-Power for alignment	None	None
Pulse width	520 ms	400 ms
IEC 60825-1 classification	Class 1 laser product	Class 1 laser product
Embedded laser class (not accessible)	3R	3R
White-to-white measurement principle	Analysis of overview image	Analysis of overview image
Power supply	External PSU: HMEG49 Medical power adapter Input: 90- 264 V AC; 47 – 63 Hz Output: 24 V DC, 2.1 A	External PSU: HMEG49 Medical power adapter Input: 90- 264 V AC; 47 – 63 Hz Output: 24 V DC, 2.1 A
Power consumption	max 35 W	max 35 W
Protection class	2	2
Protection type	IP20	IP20
Device type	B	B
Dimensions	278 x 320-400 x 502-532 mm (WxDxH)	274 mm x 316 mm x 500-530 (WxDxH)
Weight	9 kg (only measuring head)	13.2 kg

Substantial Equivalence Table (Comparing the Aberrometry and Retroillumination Imaging Technological Characteristics with the Relevant Predicate Device)

Device Type	**Applicant device**	**Predicate device** (Aberrometry, retroillumination imaging)
Model	Pentacam AXL Wave	VX120
Manufacturer name	OCULUS Optikgeraete GmbH	LUNEAU SAS
510(k) Number	TBD	K143086
	The Pentacam AXL Wave is intended to image the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens. It is indicated for the evaluation of • corneal shape, • condition of the lens (opaque crystalline lens), • the anterior chamber angle, • anterior chamber depth, • the volume of the anterior chamber, • anterior or posterior cortical opacity, • the location of cataracts using cross slit imaging with densitometry, • corneal thickness, • axial length, • white-to-white distance, • optical aberrations of the eye, • and retroillumination imaging. The Pentacam AXL Wave also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.	The VX120 is a multi-function diagnostic device combining wavefront aberrometer, corneal topographer, retro-illuminator, tonometer and pachymeter, indicated for: Measuring the refraction of the eye giving both lower and higher order aberrations Measuring the shape of the cornea Retro-illumination imaging of the eye Measuring the intraocular pressure without contacting the eye for glaucoma evaluation. Photographing the eye and taking images of the eye to evaluate the thickness of the cornea.
Aberrometry measuring principle	Hartmann-Shack aberrometer	Hartmann-Shack aberrometer
Spherical measurement range	-10D to + 6D for corneal vertex distance 12 mm	-20D to + 20D for corneal vertex distance 12 mm
Cylindrical measuring range	0D - 6D	0D – 8D
Measuring range	2.0 mm to 7.0 mm	2.0 mm to 7.0 mm
Measuring points	420 for 7 mm pupil	1400 for 7 mm pupil
Working distance	54 mm	94 mm

Device Type	**Applicant device**	**Predicate device** (Aberrometry, retroillumination imaging)
Fixation target	Illuminated slide (road with hot-air balloon)	Illuminated slide (road with hot air balloon)
Wavelength for retroillumination	850 nm	850 nm
Power supply	External PSU: HMEG49 Medical power adapter Input: 90- 264 V AC; 47 – 63 Hz Output: 24 V DC, 2.1 A	Internal PSU Input: 100-240 V AC, 50/60 Hz
Power consumption	max 35 W	300 W
Protection class	2	1
Protection type	IP20	IPX0
Device type	B	BF
Dimensions	274 mm x 316 mm x 500-530 (WxDxH)	312mm × 530mm × 570mm (WxDxH)
Weight	13.2 kg	25 kg

Principles of Operation

Like its predicates, the Pentacam AXL Wave is intended for eye examination. The Pentacam AXL Wave combines the Scheimpflug and axial length measurements functions of the Pentacam AXL and measurements of optical aberrations and retroillumination of the eye of the VX120.

The functionality is preserved for both predicate devices because the device begins by taking Scheimpflug images of the anterior segment at different axis positions during a camera rotation. After taking and processing the Scheimpflug images, the device takes measurements of the human eye to assess axial length, corneal radii, anterior chamber depth, and "white-to-white" of the human eye, as well as performing calculations for the required intraocular lens.

The wavefront measurement uses a Hartmann Shack aberrometer to detect the low and high order aberrations of the entire eye. The aberrations of the cornea, the crystalline lens and the objective refraction are calculated from this measurement.

Retroillumination can be used to show opacities of the eye. Furthermore post-op check-up of IOL inclination and centration can be performed.

1. VX120 and Pentacam AXL

The VX120 and the Pentacam AXL Wave both take measurements of the human eye to assess optical aberrations of the human eye using a wavefront sensor based on the Hartman-Shack principle.

The sensor consists of a lens mask, for example a glass plate with microlenses regularly arranged on it, and a 2D detector. If a collimated light beam from a point source falls on the lens mask, each

lens creates a point image in the focal plane, i.e. where the 2D detector is located. A wavefront creates a characteristic spot pattern on the 2D detector.

In the case of a perfect eye, the wavefront is planar and the image on the detector is an equidistant grid of spots, coinciding with the optical axes of the lenslets, usually called the reference grid. For an aberrated eye, the wavefront is distorted. The points shift from their nominal positions according to the local inclination of the wavefront above the respective microlens. The respective position of the point images can be measured with location-sensitive detectors, usually a CMOS or CCD camera chip.

Furthermore, both devices use an illumination method of a slitlamp for retroillumination. The light from a light source illuminates the eye via a beam splitter with a homogeneous spot (parallel light). The incident light is reflected by the retina and illuminates the lens of the eye from behind. Structures of the lens are imaged by the overview camera which also provides the device alignment.

2. Pentacam AXL and Pentacam AXL Wave

The Pentacam AXL and the Pentacam AXL Wave create Scheimpflug images of the anterior segment at different axis positions during a camera rotation around the eye. The images from this rotation are the basis for calculating the data from which all results are derived and for the creation of the 3D model. The entire measurement process takes less than two seconds. Up to 138,000 genuine height values are measured and analyzed. At the same time, any movements of the eye are recorded and taken into account in the calculation of the 3D model. After the PC has received the corresponding data set, it calculates the 3D model of the anterior segment. All other analyses are derived from this 3D model. The topography of the anterior and posterior corneal surface, as well as pachymetry, are calculated and displayed over the entire surface of the cornea, from limbus to limbus. An analysis of the anterior chamber results in the calculation of chamber angle, chamber volume and chamber depth. In a movable 3D model, the anterior and posterior corneal surface, iris and lens are displayed. The densitometry of the lens automatically provides quantified values. The Scheimpflug image sequence taken during an examination is digitized in the measuring head and then sent to the PC. The results of the measurements are illustrated by colored screen images (maps).

Exactly as with the cleared Pentacam AXL axial length measurement is done using a built in Michelson interferometer (optical biometry).

The axial length is measured for both devices from the front edge of the cornea to the front of the retina. Due to the motorized movable mirror (changing the geometrical path length) the interference can be detected for several eye lengths (14 – 40 mm). The electronically tracked mirror position relative to the reference arm can be used to determine the axial length of the measured eye.
Procedure for Use

The Pentacam AXL Wave and both of its predicates are primary examination devices to examine and provide data regarding eye measurements. With the Pentacam AXL and Pentacam AXL Wave, the data is transmitted to a standard computer with the Pentacam software to monitor and display

the data, images, and three-dimensional models. The models can be manipulated by a physician so that they can be viewed from different angles. The VX120 takes the measurements and provides the information through a monitor attached to the measurement part of the device.

Conclusion

The Pentacam AXL Wave is as safe and effective as the Pentacam AXL and the VX120. The Pentacam AXL Wave has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Pentacam AXL Wave and its predicate devices raise no new issues of safety or effectiveness as the device merely combines functionalities that were already cleared in the two predicate devices. Performance data demonstrates that the Pentacam AXL Wave is as safe and effective as Pentacam AXL and the VX120. Thus, the Pentacam AXL Wave is substantially equivalent.