July 14, 2021

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

Re: K202989
Trade/Device Name: Myopia Master
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: MXK, HJO
Dated: June 3, 2021
Received: June 3, 2021

Dear Randy 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,

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 Statement

510(k) Number (if known):__ K202989_____

Device Name: Myopia Master

Indications for Use:

The Myopia Master is an interferometer indicated for measuring the axial length of the eye and is intended as an aid to eye care providers.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

OCULUS Myopia Master

General Information

Applicant:

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Summary Prepared: July 13, 2021

Device Information

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

Predicate Devices

OCULUS Optikgeräte GmbH, Pentacam AXL (K152311)
OCULUS Optikgeräte GmbH, PARK 1 (K073508)

Intended Use / Indications for Use

The Myopia Master is an interferometer indicated for measuring the axial length of the eye and is intended as an aid to eye care providers.

Caution:

The measurement values of the Myopia Master are not intended to be used for refractive surgery planning (e.g. IOL calculations)

Only eyes without any ocular disease were evaluated during the clinical study performed for FDA clearance of this device, so it is unknown whether accuracy and precision when used in patients with ocular pathology will yield acceptable results. Users should interpret data cautiously when assessing eyes with ocular pathology (e.g. eyes with cataracts, corneal pathology, or post - surgical complications.

Product Description/Technological Characteristics

The OCULUS Myopia Master integrates the axial length measurement function of the cleared OCULUS Pentacam AXL (K152311) into the cleared PARK 1 device (K073508), which is an ocular device that includes Scheimpflug imaging, autorefractometry and keratometry functionalities.

The Myopia Master combines the following measuring functions in one unit: Axial length, Auto-Refractometer, Keratometer.

Auto-Refractometer

An infrared light source projects measuring light onto the retina of the eye, from which it is reflected back to the shutter location. Sensitive sensor chips, or charge-coupled device (CCD) cameras then register the deviation of the reflected light from the shutter location. The deviation depends on the ametropia. From that, an integrated microcomputer calculates the ametropia in diameter, based on the sphere, cylinder and cylinder axis position.

Keratometer

To determine the curvature of the cornea, a reflected image of the cornea is captured by a camera sensor. The reflection of test marks and of a ring is used as the reflected image, which allows the central radii of the cornea to be measured.

Axial length

The axial length of the eye is measured and displayed by a built-in Michelson interferometer.

White-to-white

The white-to-white is measured by analyzing the overview image at the end of the alignment procedure.
The image of the eye is processed by software. Edge detection provides the transition of the white scleral tissue to darker appearing cornea/iris.
By converting the pixel positions of the detected edges into millimeters, the measured value of the “white-to-white” is achieved.

Pupil

The pupil is measured by analyzing the overview image at the end of the alignment procedure. The image of the eye is processed by software. Edge detection provides the transition of the black pupil to brighter appearing cornea/iris.
By converting the pixel positions of the detected edges into millimeters, the measured value of the pupil is achieved.

Performance Data

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 2265 and IEC 60825-1 to demonstrate compliance with these standards.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Substantial Equivalence Discussion

As explained below, the Myopia Master is substantially equivalent to other legally marketed ophthalmic devices. Specifically, the Myopia Master is substantially equivalent to the predicate devices PARK 1 (K073508) and Pentacam AXL (K152311).

The Myopia Master has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate devices. Minor differences in the technological characteristics do not raise new questions of safety or efficacy. Bench and Clinical testing demonstrate that the Myopia Master is as safe and effective as its predicate devices. The inclusion of two predicates is appropriate, as all of the devices are generally intended for diagnosis in optometry and cleared under the same regulation 21 CFR 886.1850 addressing AC-powered slitlamp biomicroscopes. As described below, each of the measurements for the Myopia Master device is performed individually and is substantially equivalent in terms of technology, safety and performance to the two identified predicates.

A substantial equivalence chart comparing the similarities and differences between the Myopia Master and its predicate devices is provided below. Bench and clinical testing demonstrate that the Myopia Master is as safe and effective as its predicate devices.

1. Intended Use/ Indications for Use

<u>Indications for Use Statement for Myopia Master</u>

The Myopia Master is an interferometer indicated for measuring the axial length of the eye and is intended as an aid to eye care providers.

<u>Indications for Use Statement for PARK 1</u>

The PARK 1 is designed to photograph the eye and take Scheimpflug images of the anterior segment to evaluate the thickness of the cornea. The integrated keratometer measures the

central radii of the cornea. The implanted ophthalmic refractometer measures the refractive power of the eye.

Indications for Use Statement for Pentacam AXL

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.

The Myopia Master has nearly the same intended use as its predicate devices (to photograph the eye to measure the central radii of the cornea and the refractive power of the eye (from PARK 1) and the axial length (by optical biometry) (from the Pentacam AXL). The capabilities of the device remain the same as its predicate devices, and the device does not provide any diagnostic readouts or information. Importantly, the overall intended use of the device relative to its predicates is not modified. This intended use reflects, in practicality, the manner in which the device can be used as certain measurements are taken. The Myopia Master thus meets the first requirement for establishing substantial equivalence.

2. Technological Characteristics

The Myopia Master combines certain measurement capabilities of the cleared PARK 1 and the Pentacam AXL.

The combination of the predicates' two cleared technologies in one device does not impact the ability of either technology to operate per its separate intended use. The component technologies for the different measurements have already been used for the same purposes for which they are used in the subject device. In particular, the device incorporates the functionality of an auto-refractometer, keratometer and Michelson interferometer for axial length measurement in a single device.

Like the PARK 1, the Myopia Master consists of a measuring head which is attached to a control unit on a cross slide to align the device to the patient via joystick by the user. The patient is positioned in front of the device in a chin- and forehead rest. Both devices also use IR LEDs for eye illumination, blue slit lamps as the light source for slit illumination, and a digital CMOS camera as the overview camera.

Minor differences, such as the observation illumination being at 810 mm rather than 840 mm, and the pulse width for axial length measurements being 520 ms rather than 400 ms, 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 software for the Myopia Master is based on the software utilized with the PARK 1 predicate device. Additionally, the Myopia Master software includes the ability to measure and display axial length measurement values. The algorithms and functions for measuring, keratometry and refraction determination are unchanged from the PARK 1, while the algorithms and functions for measuring the axial length were adopted from the Pentacam AXL software.

The storage and internal communication functionalities, as well as the input and output options and functionalities, are identical to those included with the PARK 1 software, and the hardware on which the software runs is identical to that in the predicate devices. There are only minor differences in the viewing of the user interface (e.g., color changes). Certain input options have been modified to include both text and symbols.

Thus, no new or different questions of safety or effectiveness are raised by the technological characteristics of the subject device when compared to the predicates. 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.

3. Principles of Operation

Like its predicates, the Myopia Master is intended for eye examination. The Myopia Master combines the Keratometry measurement and autorefractometry measurement functionalities of PARK 1 and the axial length measurements functionality of the Pentacam AXL.

As with the PARK 1, the alignment of the device to the patient is done using an overview camera which records the eye. The images which are recorded are then analyzed by the software. Deviations from the release position of a measurement are displayed in the scan menu of the Myopia Master software. Indicators are displayed for manual alignment of the device. If the software detects the release position, the examination starts automatically.

1. PARK 1 (exempted parameters) and Myopia Master

Other Functions

Keratometer (Class I, 510(k) exempt)

Both the cleared PARK 1 and the Myopia Master determine the curvature of the cornea using a reflected cornea image which is captured by a camera sensor.

The reflections of projected spots and of a ring are in the image are analyzed by image processing. This allows the central radii of the cornea to be determined.

Autorefractometry (Class I, 510(k) exempt)

Both the cleared PARK 1 and the Myopia Master use infrared light source projections measuring light spots onto the retina of the eye from where it is reflected back to the shutter location. A CCD camera then captures the deviation of the reflected light from the shutter location. The deviation depends on the ametropia.

From that point, an integrated microcomputer calculates the ametropia in D, based on the sphere, cylinder and cylinder axis position.

2. Pentacam AXL and Myopia Master

Axial length measurement

Both the Pentacam AXL and the Myopia Master conduct axial length measurements using a built-in Michelson interferometer (optical biometry). The Michelson interferometer is a common configuration for optical interferometry. Using a semi-transparent mirror (beam splitter), the light from an infrared super luminescence diode is split into two perpendicular beams and brought to interfere after successive reflections. Both beams are reflected back towards the beam splitter which then combines their amplitudes interferometrically.

The resulting interference pattern is directed to a photoelectric detector.

Other Functions

White-to-white (Class I, 510(k) exempt)

The white-to-white is measured by analyzing the overview image at the end of the alignment procedure.
The image of the eye is processed by software. Edge detection provides the transition of the white scleral tissue to darker appearing cornea/iris.
By converting the pixel positions of the detected edges into millimeters, the measured value of the “white-to-white” is achieved.

Pupil (Class I, 510(k) exempt)

The pupil is measured by analyzing the overview image at the end of the alignment procedure.
The image of the eye is processed by software. Edge detection provides the transition of the black pupil to brighter appearing cornea/iris.
By converting the pixel positions of the detected edges into millimeters, the measured value of the pupil is achieved.

3. Procedure for Use

The Myopia Master and both of its predicates use a primary examination device to examine and provide data regarding the eye measurements. An embedded computer is used to control the device and to display the measurement results.

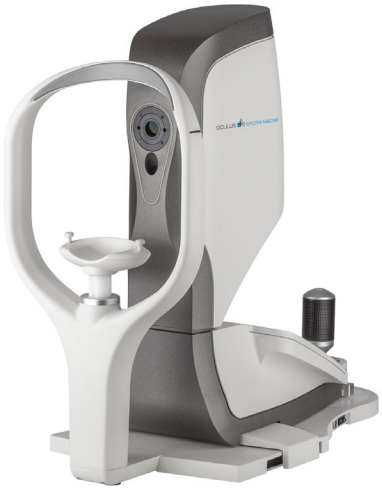
4. Conclusion

The Myopia Master has the same intended use as the PARK 1 and the Pentacam AXL and has similar indications, technological characteristics and principles of operation as both predicates. There are minor differences between the Myopia Master and its predicates, however, these differences do not raise any new or different questions of safety or effectiveness, because the new device does not add any technological characteristics that are not present in one or both of the predicate devices that are not interfered with as a result of the other features that are incorporated into the subject device. Furthermore, testing performed to evaluate the device demonstrated comparable safety and efficacy to the predicates. Thus, the Myopia Master is substantially equivalent to the PARK 1 and the Pentacam AXL.

Substantial Equivalence Table (Comparing the Technological Characteristics of the Subject Device with the Relevant Predicate Device)

Device Type	**Applicant device**	**Predicate device** (for exempted parameters)
Model	Myopia Master	PARK 1
Manufacturer name	OCULUS Optikgeräte GmbH	OCULUS Optikgeräte GmbH
510(k) Number	K202989	K073508
Intended use	The Myopia Master is an interferometer indicated for measuring the axial length of the eye and is intended as an aid to eye care providers.	The PARK 1 is designed to photograph the eye and take Scheimpflug images of the anterior segment to evaluate the thickness of the cornea. The implanted keratometer measures the central radii of the cornea. The implanted ophthalmic refractometer measures the refractive power of the eye.
Light source for alignment system	IR LED 950 nm (continuous) <0.1 mW/cm² (unweighted corneal and lenticular infrared radiation irradiance) <0.05 W/cm² (weighted retinal visible and infrared radiation thermal irradiance)	IR LED 950 nm (continuous) <0.1 mW/cm² (unweighted corneal and lenticular infrared radiation irradiance) <0.05 W/cm² (weighted retinal visible and infrared radiation thermal irradiance)
Light source for fixation target illumination (balloon slide background light)	White LED (continuous) <30 cd	White LED (continuous) <30 cd
Light source for peripheral illumination / Observation illumination	IR LED 810 nm (clocked) <50 J/cm² (weighted retinal visible and infrared radiation radiant exposure for t=200s)	IR LED 840 nm (clocked) <50 J/cm² (weighted retinal visible and infrared radiation radiant exposure t=200s)
Light source for axial length measurement	IR SLD 880 nm (continuous) <0.1 W/cm² (unweighted anterior segment visible and infrared radiation irradiance) <0.05 W/cm² (weighted retinal visible and infrared radiation thermal irradiance)	Not included
Light source for Autorefractometer	IR LED 850 nm (clocked) <0.1 J/cm² (weighted retinal visible and infrared radiation radiant exposure)	IR LED 880 nm (clocked) <0.1 J/cm² (weighted retinal visible and infrared radiation radiant exposure)
Keratometer light source	IR LED 940 nm (clocked) <$1x10^{-5}$ J/cm² (weighted retinal visible and infrared radiation radiant exposure)	IR LED 940 nm (clocked) <$1x10^{-5}$ J/cm² (weighted retinal visible and infrared radiation radiant exposure)

Device Type	**Applicant device**	**Predicate device** (for exempted parameters)
	$<1x10^{-4}$ J/cm² (unweighted corneal and lenticular infrared radiation radiant exposure)	$<1x10^{-4}$ J/cm² (unweighted corneal and lenticular infrared radiation radiant exposure)
Camera	CCD-Camera	CCD-Camera
Display	TFT on control unit	TFT on control unit
Image resolution	640 x 480 pixel	640 x 480 pixel
Measuring points	600 per image	600 per image
Image size	4.8 mm x 3.6mm	4.8 mm x 3.6 mm
Power supply	External PSU GSM60B15-P1J Medical power adapter Input: 80- 264 V AC; 47 – 63 Hz Output: 15 V DC, 4 A	External PSU GSM60B15-P1J Medical power adapter Input: 80- 264 V AC; 47 – 63 Hz Output: 15 V DC, 4 A
Power consumption	25 W	25 W
Protection class	2	2
Protection type	IP20	IP20
Applied part type	B	B
Dimensions (W x D x H)	266 x 538 x 493 – 523 mm	266 x 538 x 493 – 523 mm
Weight	12,5 kg	12 kg

Device Type	**Applicant device**	**Predicate device** (for exempted parameters)
Picture		

Substantial Equivalence Table (Comparing the Axial Length (Biometer) Technological Characteristics of the Subject Device with the Relevant Predicate Device)

Device Type	**Applicant device**	**Predicate device** (for axial length measurement function)
Model	Myopia Master	Pentacam AXL
Manufacturer name	OCULUS Optikgeraete GmbH	OCULUS Optikgeraete GmbH
510(k) Number	K202989	K152311
	The Myopia Master is an interferometer indicated for measuring the axial length of the eye and is intended as an aid to eye care providers.	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.

Device Type	**Applicant device**	**Predicate device** (for axial length measurement function)
		The Pentacam AXL also performs calculations to assist physicians in determining the power of the intraocular lens for implantation
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