DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 20, 2016

Oculus Optikgerate Gmbh
% Mr. Randy Prebula
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20016

Re: K152311
Trade/Device Name: Pentacam AXL
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: MXK, HJO
Dated: December 21, 2015
Received: December 21, 2015

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

Device Name

Pentacam® AXL

Indications for Use *(Describe)*

The Pentacam® 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,
- white-to-white distance.

The Pentacam® AXL 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

General Information

Applicant:

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Fax +49(0)641 2005-255
Summary Prepared: December 18, 2015

Device Information

Classification Name:	Device, analysis, anterior segment (AC-powered slitlamp biomicroscope)
Trade/Propriety Name:	Pentacam® AXL
Regulation Number:	886.1850
Device class:	II
Product Code:	MXK, HJO

Predicate Devices

Carl Zeiss Meditec AG, IOLMASTER 500 (K122418)
OCULUS Optikgeräte GmbH, Pentacam Scheimpflug Camera (K030719)

510(k) Summary

Intended Use / Indications for Use

The intended use of the Pentacam® AXL is defined as:

> The Pentacam® 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,
> - white-to-white distance.
>
> The Pentacam® AXL also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

Product Description/Technological Characteristics

The Pentacam AXL is designed to take photos of the anterior segment of the eye to measures eye components such as Axial length, Corneal thickness, Anterior chamber depth, Corneal curvature, Corneal cylinder, Corneal cylinder axis and White-to-white-distance. 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 captures Scheimpflug images of the anterior eye segment through varying axes. The Scheimpflug images created during an examination are transmitted to the connected PC.
The axial length of the eye is measured by interferometry.

Scheimpflug images can be captured within maximum 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.

Summary of clinical results

Comparison Pentacam AXL with IOL Master

A clinical study was performed to compare the parameters axial length (AL), corneal curvature flat meridian (Rf), corneal curvature steep meridian (Rs), corneal cylinder (Astig), corneal cylinder axis (Axis flat), anterior chamber depth (ACD), White-to-White-distance (WTW) measured by the Pentacam AXL with those obtained by the IOL Master 500 (K122418; Carl Zeiss Meditec AG, Jena, Germany) as predicate device

Eighty (80) subject eyes were assessed in the first Agreement study, 20 eyes in each of the four eye populations.

The four eye populations consisted of:

1. Normal eyes (phakic eyes without cataracts or corneal disease);
2. Eyes with cataracts;
3. Eyes with abnormal corneal shape (including eyes post-keratorefractive surgery), and
4. Eyes without a natural lens (including aphakic and pseudophakic eyes);

Eye Population total

Eighty eyes were assessed in the agreement portion of the study with IOL Master 500 as predicated device. Mean age was 49.2 ± 16.6 years (minimum age was 17, maximum 79 years).

Table 1 shows the descriptive statistics for all parameters, the mean differences ± SD, the confidence intervals for the mean differences and the Limit of Agreement for the differences.

Measure	Pentacam AXL (Mean ± SD)	IOL Master (Mean ± SD)	Difference (Mean ± SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Length [mm]	N=80 24.23 ± 1.73	N=80 24.23 ± 1.71	-0.003 ± 0.058	[-0.016; 0.010]	(-0.116; 0.110)
Radius Flat Meridian [mm]	N=76 7.86 ± 0.35	N=79 7.82 ± 0.38	0.024 ± 0.044	[0.014; 0.034]	(-0.063; 0.111)
Radius Steep Meridian [mm]	N=76 7.58 ± 0.37	N=79 7.51 ± 0.44	0.037 ± 0.058	[0.024; 0.051]	(-0.077; 0.152)
Mean Radius (Rm) [mm]	N=76 7.72 ± 0.34	N=79 7.67 ± 0.39	0.030 ± 0.038	[0.022; 0.040]	(-0.045; 0.106)
Corneal Cylinder [D]	N=76 1.6 ± 1.4	N=79 1.8 ± 1.7	-0.10 ± 0.45	[-0.20; 0.01]	(-0.99; 0.79)
Corneal Cylinder Axis [°]	N=76 102.0 ± 71.8	N=79 97.6 ± 69.6	3,6 ± 13.6	[0.4; 6.7]	(-23.0; 30.2)
Anterior Chamber Depth [mm]	N=60 3.53 ± 0.36	N=60 3.48 ± 0.36	0.05 ± 0.10	[-0.03; 0.08]	(-0.14; 0.24)
White-to White Distance [mm]	N=68 11.69 ± 0.38	N=73 11.95 ± 0.43	-0.26 ± 0.16	[-0.30; -0,22]	(-0.57; 0.04)

Eye Population Normal

Among the 80 eyes were 20 eyes of healthy patients without any known corneal pathology and without cataract. Mean age was 42.6 ± 14 years.

Table 2 shows the descriptive statistics for all parameters, the mean differences ± SD, the confidence interval for the mean differences and the Limit of Agreement for all parameters of the 20 normal eyes.

Measure	Pentacam AXL (Mean ± SD)	IOL Master (Mean ± SD)	Difference (Mean ± SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Lenght [mm]	N=20 24.22 ± 1.06	N=20 24.24 ± 1.06	-0.014 ± 0.057	[-0.041; 0.012]	-0.126; 0.098
Radius Flat Meridian [mm]	N=19 7.85 ± 0.24	N=20 7.86 ± 0.29	0.03 ± 0.03	[0.02; 0.05]	-0.03; 0.09
Radius Steep Meridian [mm]	N=19 7.66 ± 0.18	N=20 7.67 ± 0.26	0.04 ± 0.04	[0.02; 0.05]	-0.03; 0.11
Mean Radius [mm]	N=19 7.75 ± 0.20	N=20 7.76 ± 0.27	0.03 ± 0.02	[0.02; 0.04]	-0.01; 0.08
Corneal Cylinder [D]	N=19 1.03 ± 0.55	N=20 1.05 ± 0.54	-0.04 ± 0.28	[-0.18; 0.09]	-0.60; 0.51
Corneal Cylinder Axis [°]	N=19 81.7 ± 80.7	N=20 81.7 ± 79.9	5.0 ± 21.0	[-5.1; 15.2]	-36.2; 46.2
Anterior Chamber Depth [mm]	N=20 3.57 ± 0.28	N=20 3.51 ± 0.26	0.06 ± 0.09	[0.02; 0.10]	-0.12; 0.24
White-to White Distance [mm]	N=20 11.7 ± 0.3	N=14 12.0 ± 0.3	-0.24 ± 0.23	[-0.38; -0.11]	-0.70; 0.21

Eye Population Cataract

In this group patients were included with cataract but without any other known ocular pathology. Mean age of the 20 eyes was 57 ± 14 years.

Table 3 shows the descriptive statistics for all parameters, the mean difference ± SD, the confidence interval for the mean differences and the limits of agreement (LoA) for the differences of the 20 eyes with cataract.

Measure	Pentacam AXL (Mean ± SD)	IOL Master (Mean ± SD)	Difference (Mean ± SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Lenght [mm]	N=20 24.28 ± 1.24	N=20 24.27 ± 1.25	0.014 ± 0.039	[-0.004; 0.032]	-0.062; 0.091
Radius Flat Meridian [mm]	N=20 7.83 ± 0.29	N=20 7.81 ± 0.31	0.018 ± 0.048	[-0.005; 0.040]	-0.076; 0.112
Radius Steep Meridian [mm]	N=20 7.68 ± 0.28	N=20 7.65 ± 0.28	0.031 ± 0.037	[0.013; 0.048]	-0.043; 0.104
Mean Radius (Rm) [mm]	N=20 7.76 ± 0.28	N=20 7.73 ± 0.29	0.024 ± 0.033	[0.009; 0.040]	-0.041; 0.090
Corneal Cylinder [D]	N=20 0.83 ± 0.42	N=20 0.90 ± 0.60	-0.07 ± 0.28	[-0.20; 0.06]	-0.62; 0.48
Corneal Cylinder Axis [°]	N=20 102.9 ± 68.6	N=20 100.4 ± 67.3	2.6 ± 11.0	[-2.6; 7.8]	--19.1; 24.2
Anterior Chamber Depth [mm]	N=20 3.37 ± 0.39	N=20 3.29 ± 0.37	0.08 ± 0.13	[0.02; 0.14]	-0.02; 0.33
White-to White Distance [mm]	N=15 11.6 ± 0.4	N=19 11.9 ± 0.5	-0.26 ± 0.08	[-0.30; -0.21]	-0.41; -0.11

Eye Population abnormal corneal shape

In this group patients were included that had either a corneal pathology or previous refractive surgery (LASIK or PRK). Mean patient age in this subgroup was 39 ± 11 years.

Table 4 shows the descriptive statistics for all parameters, the mean differences ± SD. the confidence interval for the mean differences and the Limit of Agreement (LoA) for the differences of the 20 eyes with cataract.

Measure	Pentacam AXL (Mean ± SD)	IOL Master (Mean ± SD)	Difference (Mean ± SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Lenght [mm]	N=20 24.00 ± 1.15	N=20 23.99 ± 1.13	0.016 ± 0.030	[0.003; 0.030]	-0.042; 0.075
Radius Flat Merdian [mm]	N=17 8.02 ± 0.42	N=20 7.89 ± 0.47	0.020 ± 0.044	[-0.002; 0.042]	-0.007; 0.106
Radius Steep Meridian [mm]	N=17 7.56 ± 0.52	N=20 7.37 ± 0.64	0.051 ± 0.086	[0.006; 0.095]	-0.118; 0.219
Mean Radius [mm]	N=17 7.79 ± 0.44	N=20 7.63 ± 0.53	0.035 ± 0.047	[0.011; 0.060]	-0.129; 0.059
Corneal Cylinder [D]	N=17 2.6 ± 1.9	N=20 3.2 ± 2.3	-0.26 ± 0.69	[-0.62; 0.10]	-1.62; 1.10
Corneal Cylinder Axis [°]	N=18 107.7 ± 71.2	N=18 98.7 ± 67.7	5.0 ± 12.4	[-1.4; 11.3]	-19.4; 29.3
Anterior Chamber Depth [mm]	N=18 3.64 ± 0.37	N=18 3.63 ± 0.38	0.01 ± 0.05	[-0.01; 0.04]	-0.09; 0.12
White-to White Distance [mm]	N=18 11.9 ± 0.3	N =20 12.1 ± 0.3	-0.26 ± 0.18	[-0.35; -0.17]	-0.62; 0.10

Eyes without natural lens

In this group eyes without a natural crystalline lens were analyzed. All 20 eyes had cataract surgery before and the crystalline lens was replaced by an intraocular lens (IOL). Mean patient age was 60 ± 15 years.

Table 5 shows the descriptive statistics for all parameters. the mean difference ± SD. the confidence interval for the mean differences and the Limit of Agreement (LoA) for the differences of the 20 eyes with cataract.

Measure	Pentacam AXL (Mean ± SD)	IOL Master (Mean ± SD)	Difference (Mean ± SD)	95% CI for Mean Difference	95% LoA for Difference
Axial Length [mm]	N=20 24.40 ± 2.88	N=20 24.43 ± 2.84	-0.027 ± 0.081	[-0.066; 0.011]	-0.187; 0.132
Radius Flat Meridian [mm]	N=20 7.76 ± 0.42	N=19 7.72 ± 0.44	0.027 ± 0.054	[0.001; 0.053]	-0.079; 0.133
Radius Steep Meridian [mm]	N=20 7.40 ± 0.38	N=19 7.35 ± 0.37	0.033 ± 0.067	[0.005; 0.065]	-0.098; 0.163
Mean Radius [mm]	N=20 7.58 ± 0.37	N=19 7.54 ± 0.39	0.030 ± 0.049	[0.006; 0.054]	-0.066; 0.126
Corneal Cylinder [D]	N=20 2.1 ± 1.6	N=19 2.2 ± 1.5	-0.04 ± 0.47	[-0.26; 0.19]	-0.95; 0.88
Corneal Cylinder Axis [°]	N=14 115.5 ± 67.8	N=14 110.4 ± 64.6	1.9 ± 6.6	[-1.3; 5.1]	-11.1; 14.9
Anterior Chamber Depth [mm]	-	N=19 4.3 ± 0.61	-	-	-
White-to White Distance [mm]	N=15 11.5 ± 0.5	N=20 11.8 ± 0.5	-0.29 ± 0.08	[-0.33; -0.24]	-0.45; -0.12

The Pentacam® AXL demonstrated agreement to the IOL Master 500 (K122418; Carl Zeiss Meditec AG, Jena, Germany) for the assessment of axial length (AL), corneal curvature flat meridian (Rf), corneal curvature steep meridian (Rs), corneal cylinder (Astig), corneal cylinder axis (Axis flat), anterior chamber depth (ACD) and White-to-White-distance (WTW) parameters in normal eyes, eyes with cataracts, eyes with Abnormal corneal shape and eyes without natural lens.

Agreement between Pentacam AXL and Pentacam

In a second agreement study between the Pentacam® AXL and Pentacam® (K030719, OCULUS Optikgeräte GmbH, Wetzlar, Germany) as predicated device was tested. Both devices are using an automatic rotating Scheimpflug camera in order to derive a three dimensional model of the anterior segment. Based on this model all parameters that describe corneal shape such as mean radius of curvature or corneal thickness are calculated. The anterior chamber depth is also calculated based on the rotating Scheimpflug camera. As both devices are using the same measuring technique a high agreement between the two devices can be expected.

For this study 138 eyes of 138 patients were measured with both devices. Mean age was 69 ±11 years (youngest 26 years. oldest 90 years), 78 males (57%) and 60 (43 %) females were measured.

Table 6 shows the agreement results for the analyzed parameters Central Corneal Thickness (CCT). Radius Flat Meridian (Rf), Radius Steep Meridian (Rs), mean Radius of Curvature (Rm), Corneal Cylinder (Astigmatism) and Anterior Chamber Depth (ACD).

Measure	Pentacam AXL (Mean ± SD)	Pentacam (Mean ± SD)	Difference (Mean ± SD)	95% CI for Mean Difference	95% LoA for Difference
CCT[µm]	N=113 559 ± 34	N=120 555 ± 35	2 ± 9	[0; 4]	-15; 19
Radius Flat Meridian [mm]	N=113 7.91 ± 0.31	N=120 7.89 ± 0.31	0.011 ± 0.032	[0.005; 0.017]	-0.051; 0.074
Radius Steep Meridian [mm]	N=113 7.76 ± 0.30	N=120 7.74 ± 0.30	0.009 ± 0.040	[0.001; 0.016]	-0.071; 0.088
Mean Radius [mm]	N=113 7.83 ± 0.30	N=120 7.82 ± 0.30	0.009 ± 0.031	[0.004; 0.015]	-0.051; 0.069
Corneal Cylinder [D]	N=113 0.8 ± 0.6	N=120 0.8 ± 0.6	0.0008± 0.23	[-0.04; 0.04]	-0.46; 0.46
Anterior Chamber Depth [mm]	N=113 3.26 ± 0.41	N=120 3.20 ± 0.40	0.05 ± 0.06	[0.03; 0.06]	-0.07; 0.16

The Pentacam® AXL demonstrated agreement to the Pentacam® (K030719, OCULUS Optikgeräte GmbH, Wetzlar, Germany) for the assessment of Central Corneal Thickness (CCT), Radius Flat Meridian (Rf), Radius Steep Meridian (Rs), mean Radius of Curvature (Rm), Corneal Cylinder (Astigmatism) and Anterior Chamber Depth (ACD).

In-house Precision Testing: Results

40 eyes of 40 subjects were assessed in the Precision part of the study. To obtain repeatability values three measurements were performed on the same eye and on the same instrument under the same conditions. Mean age of the subjects involved in this study was 35 ± 9 years. 20 right and 20 left eyes were analyzed. 12 females and 28 males were involved in the study.

Table 7 shows the results of the Precision study for the analyzed parameters axial length (AL), mean radius of curvature, corneal cylinder (astigmatism), cylinder axis (axis flat meridian), central corneal thickness (CCT) and anterior chamber depth (ACD).

Measure	Number of subjects	mean	Repeatability		Reproducibility	
			SD	CV [%]	SD	CV [%]
Axial length [mm]	40	23.779	0.025	0.10	0.030	0.13
CCT[µm]	40	550	4	0.67	5	0.90
Radius flat (Rf) [mm]	40	7.85	0.012	0.15	0.017	0.21
Radius steep (Rs) [mm]	40	7.69	0.012	0.15	0.018	0.23
Mean Radius (Rm) [mm]	40	7.77	0.010	0.13	0.015	0.19
Corneal Cylinder [D]	40	0.92	0.07	7.68	0.10	10.84
Axis flat Meridian [°]	40	102.0	4.9	4.76	6.35	6.22
ACD [mm]	40	3.53	0.022	0.61	0.026	0.75
WTW [mm]	40	11.8	0.04	0.37	0.08	0.70

All parameters showed reproducibility and repeatability with coefficients of variation in most cases of less than one percent. Axial length measurement showed repeatability and reproducibility with a coefficient of variation of close to zero percent and intraclass correlation coefficients close to 1. Two parameters that had CV values above 1 percent were corneal cylinder measurements and the determination of axis of flat meridian. In both cases the coefficient of variation was still below 10 percent which is still reflecting repeatability.

Substantial Equivalence

The Pentacam® AXL is as safe and effective as the IOLMASTER 500 and the Pentacam®. The Pentacam® AXL 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 and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates that the Pentacam® AXL is as safe and effective as IOLMASTER 500 and Pentacam®. Thus, the Pentacam® AXL is substantially equivalent.