March 13, 2026

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

Re: K251848
Trade/Device Name: Pentacam® Cornea OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MXK
Dated: January 26, 2026
Received: January 26, 2026

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 (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,

BRADLEY S. CUNNINGHAM -S

CAPT Brad 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

Indications for Use Statement

510(k) Number (if known): K251848

Device Name: Pentacam® Cornea OCT

Indications for Use:

The Pentacam® Cornea OCT is a multifunction ophthalmic imaging device designed to acquire images of the anterior segment using Scheimpflug imaging (digital CMOS camera with slit-lamp illumination) and OCT.

Scheimpflug imaging provides anterior segment visualization and quantitative anterior segment measurements.

The OCT component of the system uses broadband Multi-SLD and is intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of corneal epithelium.

The Penatcam® Cornea OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases affecting the anterior segment of the eye.

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 Pentacam® Cornea OCT

K251848

General Information

Applicant

OCULUS Optikgeräte GmbH
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35582 Wetzlar
Germany
Phone: +49(0)641 2005-0
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Müncholzhäuserstr. 29
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Fax +49(0)641 2005-255
Summary Prepared: March 4, 2026

Device Information

Classification Name:	Device, tomography, optical coherence Ophthalmoscope.
Trade/Propriety Name:	Pentacam® Cornea OCT
Regulation Number:	21 C.F.R. §-886.1570
Device class:	II
Product Code:	OBO, MXK

Predicate Devices

Primary Predicate:	Optovue, Inc., SOLIX (K222166)
Reference Device:	OCULUS Optikgeräte GmbH, Pentacam® AXL Wave (K201724)

Pentacam® Cornea OCT	510(k) Summary	

Intended Use / Indications for Use

The Pentacam® Cornea OCT is a multifunction ophthalmic imaging device designed to acquire images of the anterior segment using Scheimpflug imaging (digital CMOS camera with slit-lamp illumination) and OCT.

Scheimpflug imaging provides anterior segment visualization and quantitative anterior segment measurements.

The OCT component of the system uses broadband Multi-SLD and is intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of corneal epithelium.

The Pentacam® Cornea OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases affecting the anterior segment of the eye.

Product Description/Technological Characteristics

The Pentacam® Cornea OCT combines functions of the Scheimpflug technology of the cleared Oculus GmbH Pentacam® AXL Wave device (K201724), which is used for evaluating anterior segment of the eye, with the additional functionality of optical coherence tomography (OCT). The device is intended for using both systems together (Scheimpflug imagining and OCT) by two parallel scans for evaluating anterior segment (cornea, pupil, anterior chamber and lens of the eye) of the eye by Scheimpflug and in vivo imaging, cross-sectional and three-dimensional imaging, and measurement of corneal epithelium.

While rotating around the eye, the Pentacam® Cornea OCT captures Scheimpflug images of the anterior eye segment through varying axes. The Scheimpflug images created during an examination are transmitted to the connected PC. Scheimpflug images are captured within two seconds.

Up to 138,000 (optional 276,000) 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. At same time any eye movements are recorded and taken into account. A quality specification (QS) indicates the quality of the measurement taken.

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

Spectral domain OCT technology scans in parallel with the digital CMOS camera with slit lamp illumination (Scheimpflug). OCT uses broadband Multi-SLD scan with wavelength between 780-1000nm. The OCT functionality is an addition to the prior cleared Oculus Pentacam® AXL Wave device (K201724).

The OCT system creates images (tomograms) simultaneously with the Scheimpflug system while rotating around the eye.

Three-dimensional images are obtained by scanning laterally over the sample through varying axes.

The Pentacam® Cornea OCT is specifically designed for use in scanning the corneal epithelium of the human eye. The OCT component of the system is not intended for retinal imaging or analyses.

The cornea OCT scans will be in 25 sections / sectional planes, similar to the Scheimpflug sections produced from the Scheimpflug camera and will provide an epithelial thickness map which will provide tissue thickness information in different sections.

The OCT system operates in conjunction with the Scheimpflug system, capturing images as it rotates around the eye and measures light backscattered from tissue structures

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 performed in accordance with ISO 15004-1, ISO 15004-2, ANSI Z80.36-2016 and IEC 60825-1 demonstrated compliance with these standards.

Summary of Clinical Results

Clinical Agreement and Precision Study of the Pentacam® Cornea OCT Compared to the Optovue Solix (K222166)

Clinical studies were conducted according to Clinical investigation of medical devices for human subjects – Good Clinical Practice to validate the agreement and precision of the measured parameters for the subject device Pentacam® Cornea OCT. This was a prospective, observational study conducted at a single clinical U.S. site. Eligible participants aged 22 or older were enrolled to two study group: 1) Normal – individuals with no corneal pathology, active ocular infection in either eye, no history of ocular surgery. 2) Corneal – individuals with corneal pathologies including but not limited to: Post status Laser-Assisted In Situ Keratomileusis (LASIK) surgery, Keratoconus, or other corneal dystrophies or degenerations in the study eye(s) as confirmed within the past six (6) months.

Repeatability analysis was based on the variability of repeated scans of the same eye with the same device/operator pair, while the reproducibility analysis was based on repeatability and the combined device/operator effect for multiple devices. The repeatability and reproducibility (R&R) were estimated for each study group using a random-effects analysis of variance (ANOVA) model. CV% was calculated as 100×SD/Mean; precision limits were calculated as 2.77×SD (ISO 5725-6).

Precision and agreement of the ETM between the Pentacam® Cornea OCT and the Optovue Solix were tested for 25 sections over a 7 mm diameter. The sections included a central 2mm diameter zone (C) surrounded by three annular rings (2 to 5 mm, 5 to 7 mm and 7 to 9mm), with each ring comprised of eight sections (nasal - N, superior nasal - SN, superior - S, superior temporal - ST, temporal - T, inferior temporal - IT, inferior - I, and inferior nasal - IN). The mean epithelial thickness of each section was analysed, and only measurements with sufficient quality (Quality Score OCT = “OK”) were accepted for analysis.

Scan accountability (OCT-derived epithelium thickness map): In the Normal cohort, 433 Pentacam® Cornea OCT scans were acquired to obtain 360 acceptable scans (40 eyes × 9

scans), requiring 73 repeat scans (16.9%) due to Quality Score (QS) warnings (QS = Yellow/Red). In comparison, 371 Optovue Solix scans were acquired to obtain 360 acceptable scans, requiring 11 repeat scans (3.0%) due to signal strength warnings. In the Corneal cohort, 443 Pentacam® Cornea OCT scans were acquired to obtain 360 acceptable scans, requiring 83 repeat scans (18.7%) due to QS warnings; in comparison, 376 Optovue Solix scans were acquired to obtain 360 acceptable scans, requiring 16 repeat scans (5.0%) due to signal strength warnings. All repeat scans were performed by the operator per protocol to obtain an acceptable-quality scan; no Pentacam® Cornea OCT scans were removed after investigator review. The higher repeat-scan rate observed with Pentacam® Cornea OCT is attributable to its more stringent QS criteria (including cornea centering, epithelium margin distance, analyzed area, and lost segments) and sensitivity to eyelid coverage in the superior 7–9 mm sectors, which promotes inclusion of only valid epithelial thickness data in the final analysis.

Results

For normal group: the mean age of the 40 subjects was 44.1±11.0 years, ranging from 22 years to 70 years. 19 (47.5%) right eyes and 21 (52.5%) left eyes were measured. 28 female and 12 male patients were included in the normal group.

For corneal group: The mean age of the 40 subjects (19 males – 37.5%) was 48.3 ±12.1 years, ranging from 23 to 74 years. 22 (55%) right eyes and 18 (45%) left eyes were measured. 21 female and 19 male patients were included in the corneal group.

Notes: Mean (µm) is the average epithelial thickness for the sector. Repeatability reflects within-eye repeated scans under the same configuration; Reproducibility reflects variability across configurations (different device/operator pairs).
CV% = 100×SD/Mean.

Limits were calculated as 2.77×SD per ISO 5725-6.

Pentacam® Cornea OCT precision analysis for epithelial thickness measurements in normal eyes:										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
Zone 0 to 2 mm										
C	40	55.6	1.0	2.6	1.8	[1.6;2.0]	1.3	3.7	2.5	[2.2;2.7]
Ring 2 to 5 mm										
T	40	52.9	0.9	2.5	1.7	[1.5;1.9]	1.1	3.1	2.1	[1.9;2.3]
ST	40	50.0	1.0	2.9	2.0	[1.7;2.2]	1.2	3.4	2.4	[2.1;2.6]
S	40	50.0	1.0	2.9	2.0	[1.7;2.2]	1.3	3.5	2.4	[2.1;2.6]
SN	40	52.6	1.0	2.8	1.9	[1.6;2.1]	1.2	3.4	2.3	[2.0;2.5]
N	40	55.0	1.1	3.0	2.0	[1.5;2.3]	1.4	3.9	2.6	[2.0;3.0]
IN	40	55.6	1.0	2.7	1.8	[1.5;2.0]	1.2	3.2	2.1	[1.8;2.4]
I	40	53.3	0.8	2.3	1.5	[1.2;1.7]	1.1	3.0	1.9	[1.7;2.1]
IT	40	55.6	1.0	2.7	1.8	[1.5;2.0]	1.1	3.1	2.0	[1.8;2.2]
Ring 5 to 7 mm										
T	40	55.6	1.0	2.7	1.8	[1.5;2.1]	1.1	3.1	2.1	[1.9;2.3]

Pentacam® Cornea OCT precision analysis for epithelial thickness measurements in normal eyes:										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
ST	40	52.6	1.0	2.8	1.9	[1.7;2.1]	1.3	3.5	2.5	[2.2;2.7]
S	40	50.0	1.1	3.2	2.2	[2.0;2.4]	1.5	4.2	2.9	[2.6;3.2]
SN	40	47.6	1.0	3.2	2.1	[1.8;2.4]	1.4	3.9	2.6	[2.3;2.9]
N	40	47.1	0.8	2.6	1.7	[1.3;2.0]	1.2	3.4	2.3	[1.8;2.6]
IN	40	53.3	0.8	2.2	1.5	[1.2;1.6]	1.1	3.0	1.9	[1.7;2.2]
I	40	66.7	1.0	2.3	1.5	[1.3;1.7]	1.1	3.1	2.0	[1.7;2.2]
IT	40	58.8	1.0	2.6	1.7	[1.5;1.9]	1.1	3.2	2.1	[1.8;2.3]
Ring 7 to 9 mm										
T	40	50.0	1.0	2.9	2.0	[1.7;2.2]	1.2	3.3	2.3	[2.1;2.5]
ST	40	52.4	1.1	2.9	2.1	[1.9;2.3]	1.4	3.9	2.8	[2.5;3.0]
S	35	50.0	1.7	4.6	3.4	[2.8;3.8]	1.9	5.4	4.0	[3.4;4.4]
SN	40	53.8	1.4	3.8	2.6	[2.3;2.8]	1.7	4.6	3.2	[2.9;3.4]
N	40	57.9	1.1	3.0	1.9	[1.5;2.2]	1.3	3.6	2.3	[1.9;2.5]
IN	40	56.2	0.9	2.5	1.6	[1.3;1.8]	1.2	3.3	2.2	[1.8;2.5]
I	40	52.9	0.9	2.5	1.7	[1.3;1.9]	1.3	3.6	2.4	[2.0;2.6]
IT	40	58.8	1.0	2.7	1.7	[1.5;1.9]	1.2	3.3	2.1	[1.9;2.3]

Optovue Solix precision analysis for epithelial thickness measurements in normal eyes:										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
Zone 0 to 2 mm										
C	40	54.2	1.3	3.4	2.4	[1.2; 3.1]	1.6	4.3	2.9	[1.5; 3.8]
Ring 2 to 5 mm										
T	40	52.6	1.0	3.4	1.9	[1.4; 2.3]	1.1	3.2	2.2	[1.6; 2.6]
ST	40	54.2	1.3	4.4	2.4	[1.8; 2.9]	1.4	4.0	2.8	[2.1; 3.2]
S	40	52.0	1.3	3.3	2.5	[1.8; 3.0]	1.5	4.1	2.8	[2.2; 3.3]
SN	40	53.8	1.4	3.6	2.6	[1.7; 3.1]	1.5	4.2	2.9	[2.0; 3.4]
N	40	54.5	1.2	3.9	2.2	[1.4; 2.7]	1.4	3.8	2.6	[1.8; 3.1]
IN	40	55.0	1.1	4.0	2.0	[1.3; 2.4]	1.3	3.6	2.4	[1.7; 2.9]
I	40	55.6	1.0	4.1	1.8	[1.3; 2.2]	1.2	3.2	2.2	[1.6; 2.5]
IT	40	52.9	0.9	3.3	1.7	[1.2; 2.0]	1.1	3.0	2.0	[1.6; 2.3]
Ring 5 to 7 mm										
T	40	52.0	1.3	5.3	2.5	[2.0; 3.0]	1.5	4.1	2.9	[2.3; 3.4]
ST	40	50.0	1.5	4.9	3.0	[2.6; 3.2]	1.7	4.8	3.4	[3.0; 3.8]
S	40	50.0	1.2	5.8	2.4	[1.9; 2.7]	1.4	4.0	2.8	[2.2; 3.2]
SN	40	52.4	1.1	6.6	2.1	[1.6; 2.4]	1.3	3.7	2.5	[2.0; 2.9]
N	40	52.9	0.9	5.9	1.7	[1.3; 2.0]	1.3	3.7	2.5	[1.7; 2.9]
IN	40	55.6	1.0	3.7	1.8	[1.1; 2.3]	1.3	3.5	2.3	[1.8; 2.7]

Optovue Solix precision analysis for epithelial thickness measurements in normal eyes:										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
I	40	55.6	1.0	4.4	1.8	[1.2; 2.2]	1.2	3.4	2.3	[1.6; 2.7]
IT	40	54.2	1.3	3.7	2.4	[1.4; 3.0]	1.4	3.9	2.7	[1.8; 3.3]
Ring 7 to 9 mm										
T	40	51.5	1.7	4.6	3.3	[1.9; 4.0]	1.9	5.2	3.6	[2.2; 4.4]
ST	40	50.0	1.7	5.5	3.4	[2.5; 4.0]	2.2	6.0	4.4	[3.4; 5.1]
S	40	48.8	2.1	6.1	4.3	[3.8; 4.6]	2.8	7.7	5.7	[4.8; 6.4]
SN	40	51.5	1.7	5.9	3.3	[2.5; 3.8]	2.0	5.5	3.8	[3.0; 4.4]
N	40	53.8	1.4	7.6	2.6	[2.2; 2.9]	1.7	4.8	3.1	[2.6; 3.5]
IN	40	57.1	1.2	6.1	2.1	[1.7; 2.4]	1.8	4.9	3.2	[2.5; 3.7]
I	40	52.6	1.0	4.3	1.9	[1.4; 2.3]	1.4	4.0	2.7	[2.1; 3.1]
IT	40	54.5	1.2	5.2	2.2	[1.4; 2.7]	1.5	4.1	2.7	[1.7; 3.3]

Pentacam® Cornea OCT precision analysis for ETM measurements in eyes with corneal disease										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
Zone 0 to 2 mm										
C	40	55.6	1.0	2.8	1.8	[1.6;2.0]	1.4	3.8	2.5	[2.2;2.7]
Ring 2 to 5 mm										
T	40	54.2	1.3	3.7	2.4	[1.8;2.8]	1.6	4.4	2.8	[2.2;3.3]
ST	40	55.6	1.0	2.8	1.8	[1.5;2.1]	1.3	3.5	2.3	[1.9;2.6]
S	40	52.6	1.0	2.9	1.9	[1.6;2.1]	1.4	3.9	2.5	[2.0;2.8]
SN	40	56.2	0.9	2.6	1.6	[1.4;1.8]	1.2	3.3	2.1	[1.9;2.4]
N	40	58.8	1.0	2.7	1.7	[1.5;1.9]	1.3	3.5	2.3	[2.0;2.5]
IN	40	58.8	1.0	2.7	1.7	[1.4;1.9]	1.2	3.3	2.1	[1.8;2.3]
I	40	58.8	1.0	2.7	1.7	[1.5;1.9]	1.2	3.5	2.2	[1.9;2.4]
IT	40	58.8	1.0	2.7	1.7	[1.5;1.9]	1.3	3.6	2.3	[2.1;2.5]
Ring 5 to 7 mm										
T	40	52.6	1.0	2.8	1.9	[1.7;2.0]	1.4	3.9	2.6	[2.2;2.8]
ST	40	52.6	1.0	2.8	1.9	[1.7;2.1]	1.4	3.8	2.6	[2.2;2.8]
S	40	54.2	1.3	3.5	2.4	[2.0;2.7]	1.6	4.4	3.0	[2.6;3.3]
SN	40	52.2	1.2	3.4	2.3	[1.9;2.6]	1.5	4.0	2.7	[2.0.3;3]
N	40	55.6	1.0	2.7	1.8	[1.6;2.0]	1.2	3.4	2.3	[2.0;2.5]
IN	40	52.9	0.9	2.5	1.7	[1.4;1.9]	1.2	3.4	2.2	[1.9;2.4]
I	40	52.9	0.9	2.5	1.7	[1.4;1.9]	1.3	3.7	2.4	[2.0;2.7]
IT	40	52.9	0.9	2.6	1.7	[1.5;1.9]	1.3	3.5	2.3	[2.0;2.5]
Ring 7 to 9 mm										
T	40	52.2	1.2	3.3	2.3	[1.8;2.6]	1.5	4.1	2.8	[2.3;3.2]

Pentacam® Cornea OCT precision analysis for ETM measurements in eyes with corneal disease										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
ST	40	48.0	1.2	3.5	2.5	[1.9;2.9]	1.6	4.4	3.1	[2.5;3.6]
S	38	50.0	1.6	4.4	3.2	[2.6;3.6]	2.1	5.7	4.1	[3.3;4.7]
SN	39	53.8	1.4	3.8	2.6	[2.2;3.0]	1.7	4.6	3.2	[2.8;3.6]
N	40	53.8	1.4	3.9	2.6	[1.9;3.0]	1.7	4.8	3.2	[2.3;3.7]
IN	40	52.4	1.1	3.1	2.1	[1.8;2.4]	1.3	3.7	2.5	[2.1;2.9]
I	40	52.0	1.3	3.7	2.5	[1.9;2.9]	1.4	4.0	2.7	[2.2;3.1]
IT	40	52.4	1.1	3.1	2.1	[1.7;2.3]	1.3	3.7	2.5	[2.2;2.7]

Optovue Solix precision analysis for ETM measurements in eyes with corneal disease:										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
Zone 0 to 2 mm										
C	40	54.5	1.2	3.4	2.2	[1.3; 2.7]	1.4	3.9	2.5	[1.7; 3.0]
Ring 2 to 5 mm										
T	40	54.5	1.2	3.4	2.2	[1.7; 2.6]	1.4	4.0	2.6 [2.2; 2.9]	
ST	40	55.2	1.6	4.4	2.9	[1.8; 3.6]	1.8	5.1	3.4	[2.3; 4.0]
S	40	54.5	1.2	3.3	2.2	[1.8; 2.5]	1.5	4.0	2.7	[2.2; 3.1]
SN	40	54.2	1.3	3.6	2.4	[1.6; 2.9]	1.6	4.6	3.0	[1.9; 3.7]
N	40	56.0	1.4	3.9	2.5	[1.7; 3.1]	1.8	4.9	3.2	[2.0; 3.9]
IN	40	57.7	1.5	4.0	2.6	[1.5; 3.2]	1.7	4.8	3.1	[2.0; 3.7]
I	40	57.7	1.5	4.1	2.6	[1.6; 3.2]	1.7	4.6	3.0	[2.1; 3.5]
IT	40	57.1	1.2	3.3	2.1	[1.6; 2.5]	1.5	4.1	2.6	[2.0; 3.1]
Ring 5 to 7 mm										
T	40	52.0	1.3	3.7	2.5	[1.9; 3.0]	2.0	5.5	3.8	[2.7; 4.5]
ST	40	51.4	1.9	5.3	3.7	[2.3; 4.5]	2.2	6.2	4.3	[3.2; 5.1]
S	40	51.4	1.8	4.9	3.5	[2.8; 3.9]	2.1	5.9	4.2	[3.5; 4.7]
SN	40	52.5	2.1	5.8	4.0	[2.7; 4.8]	2.5	7.0	4.9	[3.0; 6.0]
N	40	54.5	2.4	6.6	4.4	[2.2; 5.6]	2.8	7.8	5.3	[2.8; 6.6]
IN	40	53.8	2.1	5.9	3.9	[1.8; 5.0]	2.4	6.6	4.4	[2.7; 5.5]
I	40	54.2	1.3	3.7	2.4	[1.9; 2.8]	1.8	4.9	3.3	[2.8; 3.7]
IT	40	53.3	1.6	4.4	3.0	[2.1; 3.5]	1.9	5.2	3.5	[2.6; 4.1]
Ring 7 to 9 mm										
T	40	51.5	1.7	4.6	3.3	[2.1; 4.0]	2.4	6.8	4.8	[3.0; 5.8]
ST	40	48.8	2.0	5.5	4.1	[2.7; 4.9]	2.3	6.4	4.7	[3.5; 5.6]
S	38	47.8	2.2	6.1	4.6	[3.8; 5.2]	2.8	7.7	5.8	[4.8; 6.5]
SN	39	50.0	2.1	5.9	4.2	[2.9; 5.0]	2.7	7.5	5.3	[3.5; 6.4]

Optovue Solix precision analysis for ETM measurements in eyes with corneal disease:										
Sections	Number of Subjects	Mean (µm)	Repeatability				Reproducibility			
			SD	Limit	CV (%)	95% CI	SD	Limit	CV (%)	95% CI
N	40	52.9	2.7	7.6	5.1	[3.2; 6.3]	3.3	9.1	6.1	[3.9; 7.5]
IN	40	53.7	2.2	6.1	4.1	[2.2; 5.1]	2.5	7.0	4.8	[3.5; 5.8]
I	40	50.0	1.5	4.3	3.0	[2.4; 3.5]	1.9	5.4	3.8	[3.0; 4.3]
IT	40	54.3	1.9	5.2	3.5	[2.4; 4.2]	2.2	6.0	4.0	[2.8; 4.8]

The study demonstrated high repeatability and reproducibility of epithelial thickness measurements across corneal zones in both normal and corneal pathology groups, supporting the clinical utility of the device.

Repeatability and reproducibility CV (%) values remained below the predefined performance goals.

Agreement analysis was done based on the same 40 healthy patients of the precision part of the study (normal group). The mean age of the 40 subjects (12 males and 28 females) was 44.1 ± 11.0 years, ranging from 22 to 70 years. 19 (47.5 %) right eyes and 21 (52.5 %) left eyes were measured.

The agreement of the Pentacam® Cornea OCT and the Optovue Solix was analyzed using the first paired acceptable scans-- defined as the earliest configuration in which both the test and predicate device have acceptable scans in the same configuration.

Results of the Bland-Altman analysis for the agreement between Pentacam® Cornea OCT and Optovue Solix for normal group. Mean difference was calculated by subtracting the corneal epithelium thickness of the Optovue Solix from the Pentacam® Cornea OCT (Pentacam® Cornea OCT minus Optovue Solix). All values are given in µm. Confidence intervals are calculated based on bootstrapping method					
Sections	Difference (Mean ±SD)	95% CI for Mean Difference	95% LoA (Lower; Upper)	95% CI for Lower LOA	95% CI for Upper LoA
Zone 0 to 2mm					
C	0.2 ±2.2	-0.5 ; 0.8	-4.1 ; 4.4	-5.8 ; -2.5	3.1 ; 5.6
Ring 2 to 5mm					
T	1.1 ±1.6	0.6 ; 1.6	-2.0 ; 4.1	-2.6 ; -1.3	3.3 ; 4.8
ST	1.0 ±2.0	0.4 ; 1.6	-2.9 ; 4.8	-3.9 ; -1.7	3.6 ; 6.0
S	1 .0±2.0	0.4 ; 1.6	-2.8 ; 4.9	-3.8 ; -1.8	4.0 ; 5.6
SN	0.9 ±1.6	0.5 ; 1.4	-2.2 ; 4.0	-3.0 ; -1.2	3.3 ; 4.6
N	1.0 ±1.3	0.6 ; 1.4	-1.7 ; 3.6	-2.3 ; -1.0	2.8 ; 4.3
IN	1.3 ±1.4	0.8 ; 1.7	-1.5 ; 4.0	-2.2 ; -0.6	3.3 ; 4.6
I	1.4 ±1.2	1.1 ; 1.8	-0.9 ; 3.8	-1.5 ; -0.3	3.2 ; 4.3
IT	1.3 ±1.5	0.9 ; 1.8	-1.6 ; 4.2	-2.1 ; -0.9	3.4 ; 4.7
Ring 5 to 7mm					
T	1.0 ±1.8	0.4 ; 1.5	-2.6 ; 4.6	-3.3 ; -1.7	3.6 ; 5.4
ST	1.3 ±2.3	0.6 ; 2.0	-3.2 ; 5.7	-4.2 ; -2.1	4.6 ; 6.6
S	0.6 ±2.4	-0.2 ; 1.3	-4.2 ; 5.3	-5.6 ; -2.7	3.9 ; 6.6

Results of the Bland-Altman analysis for the agreement between Pentacam® Cornea OCT and Optovue Solix for normal group. Mean difference was calculated by subtracting the corneal epithelium thickness of the Optovue Solix from the Pentacam® Cornea OCT (Pentacam® Cornea OCT minus Optovue Solix). All values are given in µm.
Confidence intervals are calculated based on bootstrapping method

Sections	Difference (Mean ±SD)	95% CI for Mean Difference	95% LoA (Lower; Upper)	95% CI for Lower LOA	95% CI for Upper LoA
SN	0.9 ±1.7	0.4 ; 1.5	-2.4 ; 4.2	-3.1 ; -1.5	3.5 ; 4.9
N	0.9 ±1.6	0.4 ; 1.4	-2.3 ; 4.1	-3.1 ; -1.3	3.0 ; 5.2
IN	1.1 ±1.6	0.7 ; 1.7	-2.1 ; 4.3	-2.9 ; -1.1	3.3 ; 5.5
I	1.4 ±1.7	0.9 ; 1.9	-1.9 ; 4.7	-2.7 ; -0.9	3.9 ; 5.5
IT	1.3 ±1.8	0.7 ; 1.8	-2.2 ; 4.8	-3.1 ; -1.2	3.9 ; 5.4
Ring 7 to 9mm					
T	0.8 ±2.2	0.1 ; 1.5	-3.5 ; 5.1	-4.3 ; -2.5	3.6 ; 6.4
ST	1.5 ±2.4	0.8 ; 2.2	-3.3 ; 6.2	-4.3 ; -2.2	4.9 ; 7.4
S	0.7 ±4.0	-0.6 ; 1.9	-7.1 ; 8.4	-8.8 ; -4.9	6.1 ; 10.4
SN	0.7 ±2.6	-0.1 ; 1.5	-4.4 ; 5.8	-5.5 ; -2.8	4.6 ; 6.8
N	0.0 ±3.2	-1.0 ; 0.9	-6.2 ; 6.1	-7.9 ; -4.2	4.0 ; 8.3
IN	0.5 ±2.2	-0.2 ; 1.2	-3.8 ; 4.8	-5.4 ; -2.5	3.3 ; 6.0
I	1.0 ±2.1	0.4 ; 1.6	-3.2 ; 5.1	-4.2 ; -2.0	3.5 ; 6.5
IT	0.7 ±1.9	0.1 ; 1.2	-3.1 ; 4.4	-4.0 ; -2.1	3.4 ; 5.2

Independent of the statistical method, the upper CI of the upper LOA as well as the lower CI of the lower LOA were within the predefined performance goals for all sectors. Furthermore, the test device showed a very high agreement with very small mean deviations in all sectors. The mean differences between the devices were consistently below 2µm across all sections.

Agreement analysis was done based on the same 40 cornea patients of the precision part of the study (cornea group).The mean age of the 40 subjects (19 males - 47,5%, 21 females - 52,5 %) was 48.3 ±12.1 years, ranging from 23 to 74 years. 22 (55 %) right eyes and 18 (45 %) left eyes were measured.

Similar to the normal group, the agreement of the Pentacam® Cornea OCT and the Optovue Solix was analyzed using the first paired acceptable scans—defined as the earliest configuration in which both the test and predicate device have acceptable scans in the same configuration.

Results of the Bland-Altman analysis for the agreement between Pentacam® Cornea OCT and Optovue Solix for cornea group. Mean difference was calculated by subtracting the corneal epithelium thickness of the Optovue Solix from the Pentacam® Cornea OCT (Pentacam® Cornea OCT minus Optovue Solix). All values are given in µm. Confidence intervals are calculated based on bootstrapping method.

Sections	Difference (Mean ±SD)	95% CI for Mean Difference	95% LoA (Lower; Upper)	95% CI for Lower LOA	95% CI for Upper LoA
Zone 0 to 2mm					
C	0.2 ± 2	-0.4 ; 0.8	-3.7 ; 4.0	-4.5 ; -2.7	2.7 ; 5.0
Ring 2 to 5mm					

Results of the Bland-Altman analysis for the agreement between Pentacam® Cornea OCT and Optovue Solix for cornea group. Mean difference was calculated by subtracting the corneal epithelium thickness of the Optovue Solix from the Pentacam® Cornea OCT (Pentacam® Cornea OCT minus Optovue Solix). All values are given in µm. Confidence intervals are calculated based on bootstrapping method.

Sections	Difference (Mean ±SD)	95% CI for Mean Difference	95% LoA (Lower; Upper)	95% CI for Lower LOA	95% CI for Upper LoA
T	0.5 ± 2.9	-0.5 ; 1.3	-5.2 ; 6.1	-8.1 ; -2.4	4.2 ; 7.9
ST	1.6 ± 2.5	0.8 ; 2.4	-3.3 ; 6.5	-4.7 ; -1.7	4.6 ; 8.3
S	1.9 ± 2.2	1.2 ; 2.6	-2.5 ; 6.3	-3.6 ; -1.3	4.5 ; 7.8
SN	1.6 ± 1.9	1.0 ; 2.2	-2.1 ; 5.2	-2.7 ; -1.3	4.0 ; 6.2
N	1.0 ± 1.8	0.4 ; 1.6	-2.5 ; 4.4	-3.3 ; -1.6	3.4 ; 5.3
IN	1.0 ± 2.1	0.4 ; 1.6	-3.0 ; 5.1	-4.3 ; -1.7	4.0 ; 6.0
I	0.8 ± 2.4	0.0 ; 1.5	-4.0 ; 5.5	-5.8 ; -2.4	4.0 ; 6.8
IT	0.7 ± 2.2	0.0 ; 1.4	-3.7 ; 5.1	-5.5 ; -1.9	3.4 ; 6.5
Ring 5 to 7mm					
T	1.7 ± 2.4	0.9 ; 2.4	-3.0 ; 6.4	-4.5 ; -1.5	4.6 ; 7.9
ST	2.1 ± 2.8	1.4 ; 3.1	-3.4 ; 7.7	-4.9 ; -1.6	5.2 ; 10.1
S	2.6 ± 3.4	1.6 ; 3.7	-4.1 ; 9.2	-6.0 ; -1.9	6.7 ; 12.0
SN	2.1 ± 2.3	1.4 ; 2.8	-2.4 ; 6.7	-3.8 ; -1.0	5.2 ; 7.9
N	1.2 ± 2.5	0.3 ; 1.9	-3.7 ; 6.1	-5.3 ; -1.9	4.4 ; 7.5
IN	1.0 ± 2.1	0.4 ; 1.6	-3.1 ; 5.1	-3.8 ; -2.2	3.8 ; 6.2
I	0.9 ± 2.9	-0.1 ; 1.7	-4.8 ; 6.5	-6.8 ; -2.7	4.8 ; 8.1
IT	1.7 ± 2.6	0.9 ; 2.6	-3.4 ; 6.8	-4.3 ; -2.2	4.8 ; 8.5
Ring 7 to 9mm					
T	1.1 ± 2.6	0.4 ; 2.0	-3.9 ; 6.2	-5.5 ; -1.9	3.8 ; 8.6
ST	1.7 ± 3.1	0.9 ; 2.7	-4.3 ; 7.8	-5.9 ; -2.3	4.9 ; 10.6
S	1.8 ± 4.1	0.5 ; 3.2	-6.4 ; 9.9	-8.3 ; -4.1	6.3 ; 12.8
SN	1.0 ± 2.3	0.3 ; 1.8	-3.4 ; 5.5	-4.5 ; -2.1	3.7 ; 7.2
N	1.6 ± 3.6	0.6 ; 2.7	-5.5 ; 8.7	-7.9 ; -2.4	5.3 ; 12.6
IN	0.5 ± 2.8	-0.4 ; 1.3	-5.1 ; 6.0	-7.6 ; -2.5	4.1 ; 7.6
I	-0.1 ± 3.6	-1.3 ; 0.9	-7.2 ; 6.9	-10.8 ; -3.4	4.3 ; 9.0
IT	0.8 ± 3.0	-0.1 ; 1.7	-5.0 ; 6.6	-6.2 ; -3.4	5.0 ; 8.0

Similar to the normal group, the upper CI of the upper LOA as well as the lower CI of the lower LOA in the cornea cohort remained within the predefined performance goals for all sectors. Furthermore, the test device showed consistently high agreement with the predicate device, with minimal deviations. The mean differences between the devices were uniformly small – remaining below 2 µm across all sections—indicating negligible measurement bias and strong concordance throughout the corneal regions.

Substantial Equivalence

Pentacam® Cornea OCT	510(k) Summary	OCULUS

As explained below, the Pentacam® Cornea OCT is substantially equivalent to other legally marketed ophthalmic devices. Specifically, the Pentacam® Cornea OCT is substantially equivalent to the predicate device Optovue Solix OCT (K222166). The Pentacam® Cornea OCT has the same intended use and similar indications, technological characteristics, and principles of operation related to optical coherence tomography (OCT) imaging and measurement of corneal as the legally marketed Solix OCT device.

The Pentacam® Cornea OCT also incorporates Scheimpflug-based imaging and biometry functions that are consistent with those of the previously cleared Pentacam® AXL Wave (K201724), which is identified as a reference device. These secondary functions support anterior segment analysis and do not alter the primary OCT-based imaging function.

Minor differences in technological characteristics between the Pentacam® Cornea OCT and the identified predicate devices do not raise new or different questions of safety or effectiveness. Bench and clinical testing demonstrate that the Pentacam® Cornea OCT is as safe and effective as the predicate devices for its intended use.

A substantial equivalence chart comparing the similarities and differences between the Pentacam® Cornea OCT and its predicate and reference devices is provided below.

Comparison of OCT Technological Characteristics

	Subject Device	Predicate Device (Optovue Solix)	Substantial Equivalence Comparison
	Pentacam® Cornea OCT	Optovue Solix	
Regulation	21 CFR 886.1570	21 CFR 886.1570	Same
Product Code	OBO, MXK	OBO, HKI	Same
510(k) Number	TBD	K222166	NA
Classification	II	II	Same
Classification Name	Ophthalmoscope, Ophthalmic camera	Ophthalmoscope, Ophthalmic camera	Same
Intended Use	The OCT system is intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of corneal epithelium. It is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases.	SOLIX is an optical coherence tomography system intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, corneal epithelium, corneal stroma, pachymetry, and anterior chamber of the eye	Different The same for the claimed subset of corneal structures.
Indications for Use	The Pentacam® Cornea OCT is a multifunction ophthalmic imaging device designed to acquire images of the anterior segment using Scheimpflug imaging (digital CMOS camera with slit-lamp illumination) and OCT.	SOLIX is an optical coherence tomography system intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex	Different The Pentacam Cornea OCT is only for the corneal structure of an eye, a subset of the kinds of images and uses included in the cleared reference device.

	Subject Device	Predicate Device (Optovue Solix)	Substantial Equivalence Comparison
	Pentacam® Cornea OCT	Optovue Solix	
	Scheimpflug imaging provides anterior segment visualization and quantitative anterior segment measurements. The OCT component of the system uses broadband Multi-SLD and is intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of corneal epithelium. The Pentacam® Cornea OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases affecting the anterior segment of the eye.	(GCC), optic disc, cornea, corneal epithelium, corneal stroma, pachymetry, and anterior chamber of the eye. With the integrated reference database, SOLIX is also a quantitative tool for the comparison of the retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of known normal subjects. It is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases. The SOLIX with the AngioVue software feature is indicated as an aid in the visualization of vascular structures of the retina and choroid in normal subjects, and in subjects with glaucoma and retinal diseases. The AngioAnalytics software feature of AngioVue is indicated for the measurement of vascular density, the foveal avascular zone, the thickness of retinal layers, and nerve fiber layer, and measurement of optic disc parameters in normal subjects, and in subjects with glaucoma and retinal diseases.	
Technological Characteristics	Spectral-Domain Optical Coherence Tomography (SD-OCT)	Spectral-Domain Optical Coherence Tomography (SD-OCT)	Same
System Components	- Forehead rest - Measuring window - Scheimpflug camera - Chin rest - Twist grip - Cross slide - Base unit (measuring box) - Power supply - Sliding plate with circle marks - Joystick - Computer with Windows operating system	- Scanner - Control Unit - Chin and Head rest - Joystick and base assembly - Computer with Windows operating system - Monitor - Keyboard and Mouse - System Table - CAM Lens FullRange - CAM Lens	Different due external design of the device
Signal Type	Optical scattering from tissue for OCT	Optical scattering from tissue for OCT	Same
OCT Light Source	Superluminescent diode (SLD) 780-1000 nm	Superluminescent diode (SLD) 840nm	Same

Pentacam® Cornea OCT	510(k) Summary	OCULUS

	Subject Device	Predicate Device (Optovue Solix)	Substantial Equivalence Comparison
	Pentacam® Cornea OCT	Optovue Solix	
OCT Optical Power	Max. 1.2mW	1.45mW (at cornea)	Different Pentacam has an optical set up including detector which reduces the required power output. This does not raise different questions of safety or effectiveness, safety was proved by compliance with respective standards IEC 60825-1 and ANSI Z.80.36
Fixation Light Source	Red LED	Blue LED	Different Red fixation light is a standard for Pentacam models. It does not affect scanning.
IR Fundus Imaging Light Source	Not Applicable	NIR LED	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Iris Viewer Illumination	IR LED	IR LED	Same
Working Distance	45 mm	Retina imaging: 35 mm With CAM (Cornea Anterior Module) attached: 20mm	Different Distance of the front of the device and patient's eye and due to optical set up. The working distance depends on the respective imaging optics. Both 45mm and 80mm represent safe distances in terms of not accidentally touching the eye. This does not raise different questions of safety or effectiveness.
Ergonomic	Forehead rest Joystick	Chin and forehead rest Joystick for alignment on the eye	Same
Electrical	Medical-grade power supply (IEC 60601 compliant)	Medical-grade power supply (IEC 60601 compliant)	Same
Cleaning and Disinfection	Chin and forehead rest can be cleaned with a disinfecting agent, such as isopropyl alcohol wipes or a germicide with a lint-free cloth.	Chin and forehead rest can be cleaned with a disinfecting agent, such as isopropyl alcohol wipes or a germicide with a lint-free cloth.	Same
Axial Resolution (in tissue)	≤2 µm	5µm	Different Imaging resolutions in Pentacam® Cornea OCT is higher but the differences do not raise different questions of safety or effectiveness.
Scan Rate	50,000 A-Scan/second	120,000 A-Scan/second	Different For the application of the Pentacam® Cornea OCT (cornea) and the different scanning patterns (including their geometries), a lower A-scan rate

	Subject Device	Predicate Device (Optovue Solix)	Substantial Equivalence Comparison
	Pentacam® Cornea OCT	Optovue Solix	
			is sufficient/appropriate. A higher scan rate would reduce the signal-to-noise ratio. The difference does not raise different questions of safety or effectiveness.
Scan Depth	3.6 mm	~up to 3 mm except full- range scans up to 6.25 mm such as FullRangeTM Retina and FullRangeTM AC scans	Different Scan only cornea of an eye so the scan depth is smaller. The difference does not raise different questions of safety or effectiveness.
AngioVue (wider FOV)	Not Applicable	AngioVue 12mm	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
AngioVue (wider FOV)	Not Applicable	AngioVue 9mm	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
AngioVue	Not Applicable	AngioVue Retina	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
AngioVue	Not Applicable	AngioVue 3mm	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
AngioVue	Not Applicable	AngioVue Disc	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Retina	Not Applicable	Line	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Retina	Not Applicable	Full Range Retina	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Retina	Not Applicable	Retina Cube	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Retina	Not Applicable	Raster	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Retina	Not Applicable	Radial Lines	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Nerve Fiber	Not Applicable	Disc Cube	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Retina	Not Applicable	Wellness	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Cornea	Epithelium Map	Corneal Map	Same Different naming
Cornea	3D scan	Anterior Radial	Same

	Subject Device	Predicate Device (Optovue Solix)	Substantial Equivalence Comparison
	Pentacam® Cornea OCT	Optovue Solix	
			Different naming
Cornea	Averaging mode	Cornea Line	Same Different naming
Cornea	Not Applicable	Cornea Angle	Not Applicable The Pentacam® Cornea OCT has not this scanning mode of cornea.
Cornea	Sector scan	Cornea Cube	Same Different naming
Cornea	Not Applicable	Full Range AC	Not Applicable The Pentacam® Cornea OCT has not this scanning mode of cornea.
Motion Artifacts Reduction	Image registration	Tracking based on IR fundus image + MCT	Different The difference is based on software. The difference does not raise different questions of safety or effectiveness.
Post- Processing for OCT Scans	Segmentation and analysis of OCT Scans for Cornea Epithelium thickness map	• Segmentation and analysis of OCT Scans for Retina and Nerve Fiber • Segmentation and analysis of OCT Scans for Cornea • Scan Quality • Manual editing of segmentation error and propagation of manual correction to neighboring B-scans • Projection artifacts removal (PAR) • Visualization and qualitative analysis of retinal and vascular structures based on en face images	Same for applicable cornea scans The Pentacam® Cornea OCT is intended for cornea only. NA for posterior scans
Post-Processing for OCT Scans	Not Applicable OCT scans only for anterior segment of the eyes	Feature under AngioAnalytics license: • Quantitative analysis of vascular structures based on en face images • Quantitative analysis of retinal, nerve fiber, and optic disc structure • Fovea detection • Optic disc margin detection	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.
Reference Database (RDB)	Not Applicable	OCT structural RDB Collected for the following scans: AngioVue Retina, AngioVue Disc, Retina Cube Disc Cube and Wellness scans • No OCT Angiography RDB available	Not Applicable The Pentacam® Cornea OCT is intended for cornea only.

	Subject Device	Predicate Device (Optovue Solix)	Substantial Equivalence Comparison
	Pentacam® Cornea OCT	Optovue Solix	
Device Packaging and Sterilization	The device is not sterile, does not require sterilization, and does not include shelf-life claims on product labeling. Shipping packaging has been designed to safely transport the device to the end user facility.	The device is not sterile, does not require sterilization, and does not include shelf-life claims on product labeling. Shipping packaging has been designed to safely transport the device to the end user facility.	Same

Comparison of Scheimpflug Imaging (Tomographic) Technological Characteristics

	Applicant Device	Reference Device (Scheimpflug Imaging, Etc.)	Substantial Equivalence Comparison
Model	Pentacam® Cornea OCT	Pentacam® AXL Wave	NA
Manufacturer name	OCULUS Optikgeraete GmbH	OCULUS Optikgeraete GmbH	Same
510(k) Number	TBD	K201724	NA
Product code	OBO, MXK	MXK, HJO	
Classification	II	II	Same
Classification Name	AC-Powered Slitlamp Biomicroscope	AC-Powered Slitlamp Biomicroscope	Same
	The Pentacam® Cornea OCT is a multifunction ophthalmic imaging device designed to acquire images of the anterior segment using Scheimpflug imaging (digital CMOS camera with slit-lamp illumination) and OCT. Scheimpflug imaging provides anterior segment visualization and quantitative anterior segment measurements. The OCT component of the system uses broadband Multi-SLD and is intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of corneal epithelium.. The Pentacam® Cornea OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases affecting the anterior segment of the eye.	The Pentacam® AXL Wave 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 - optical aberrations of the eye, - retroillumination imaging.	Different For Scheimpflug imaging the additional information was added to Intended Use of Applicant Device. The information is about how the image is captured (camera type). Both predicate and applicant devices use identical camera and image capture method. This additional information does not raise new or different questions of safety and effectiveness. Pentacam® Cornea OCT does not have retroillumination imaging, optical aberrations and optical biometry. The absence of these functions does not raise new or different questions of safety and effectiveness. Pentacam® Cornea OCT has an additional indication related with OCT imaging, which has previously been cleared by FDA and which does not raise new or different questions of safety and effectiveness, as supported by the Solix reference device.

	Applicant Device	Reference Device (Scheimpflug Imaging, Etc.)	Substantial Equivalence Comparison
		The Pentacam® AXL Wave also performs calculations to assist physicians in determining the power of the intraocular lens for implantation	
Scheimpflug Camera	Digital CMOS camera	Digital CMOS camera	Same
Resolution of Scheimpflug camera	1360x1024 pixel (active)	1392x1040 pixel (effective) 1360x1024 pixel (active)	Same
Slit length	28 mm	14 mm	Different Minor difference Different illumination opening widths and optical structures. This does not raise different questions of safety or effectiveness, safety was proved by compliance with respective standards IEC 60825-1 and ANSI Z.80.36
Slit width	35 µm	35 µm	Same
Light source for slit illumination	Blue slit lamp (LED 470 nm)	Blue slit lamp (LED 470 nm)	Same
Light source for eye illumination	4 IR LEDs (840 nm)	4 IR LEDs (810 nm)	Different Adapted for the optical beam path with tailored coatings and filters to enable multiple measurement or imaging modalities within the same optical path. This does not raise different questions of safety or effectiveness, safety was proved by compliance with respective standard ANSI Z.80.36
Images	Up to 100 in 2 seconds (Standard mode 25 in 1 seconds; cornea fine mode 50/100 in 2 seconds)	Up to 100 in 2 seconds (Standard mode 25 in 1 seconds; cornea fine mode 50/100 in 2 seconds)	Same
Rotation	Up to 180°	Up to 180°	Same Within half a turn, 360° of the patient's eye can be captured
Measuring points	up to138,000 (optional 276,000)	up to 138,000	Same
Working distance	45 mm	80 mm	Different Distance of the front of the device and patient's eye and due to optical set up. The working distance depends on the respective imaging optics. Both 45mm and 80mm represent safe distances in terms of not accidentally

	Applicant Device	Reference Device (Scheimpflug Imaging, Etc.)	Substantial Equivalence Comparison
			touching the eye. This does not raise different questions of safety or effectiveness.
Physical principle	Scheimpflug principle / Spectrometer	Scheimpflug principle / Optical interferometer	Different Pentacam® Cornea OCT has an additional measuring modality related with OCT imaging, which has previously been cleared by FDA and which does not raise new or different questions of safety and effectiveness, as supported by the Solix reference device.
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	Same
Auto release function	Yes	Yes	Same
Auto movement system	No	No	Same
Fixation light	Yes, red LED (640 nm)	Yes, red LED (640 nm)	Same
Overview camera	Digital CMOS camera	Digital CMOS camera	Same
Resolution of overview camera	1280 x 960	1280 x 960	Same
Measurement range - Axial length	NA	14 – 40 mm	NA The Pentacam® Cornea OCT does not have functionality to measure the axial length. Absence of this function does not raise new or different questions of safety and effectiveness.
Light source for interferometer	NA	IR Super luminescence diode (SLD)	NA The Pentacam® Cornea OCT does not have an interferometer. Absence of interferometer does not raise new or different questions of safety and effectiveness.
Wavelength	NA	880 nm	NA The Pentacam® Cornea OCT does not have an interferometer. Absence of interferometer does not raise new or different questions of safety and effectiveness.
SLD-Power for measurement	NA	0.7 mW	NA The Pentacam® Cornea OCT does not have an interferometer.

	Applicant Device	Reference Device (Scheimpflug Imaging, Etc.)	Substantial Equivalence Comparison
			Absence of interferometer does not raise new or different questions of safety and effectiveness.
Pulse width	NA	520 ms	NA The Pentacam® Cornea OCT does not have an interferometer. Absence of interferometer does not raise new or different questions of safety and effectiveness.
IEC 60825-1 classification	Class 1 laser product	Class 1 laser product	Same
Embedded laser class (not accessible)	3B	3R	Different Usage of a light source capable of emitting higher light energy if not embedded, while operating within the limits of a Class I laser product under normal conditions (like the predicate) This does not raise different questions of safety or effectiveness, safety was proved by compliance with respective standard IEC 60825-1.
White-to-white measurement principle	Analysis of overview image	Analysis of overview image	Same
Power supply	Externa PSU: GSM90B24-P1M (10029038) Input: 100 - 240 V AC, 50/60 Hz Output: 24 V DC, 3.75 A	External PSU: HMEG49 Medical power adapter Input: 90- 264 V AC; 47 – 63 Hz Output: 24 V DC, 2.1 A	Different The increased power consumption of the applicant device is attributable to a greater rotating mass and more advanced electronics. This does not raise different questions of safety or effectiveness, safety was proved by compliance with respective standards AAMI/ANSI 60601-1 and IEC 60601-1-2.
Power consumption	max 75 W	max 35 W	Different The increased power consumption is attributable to a greater rotating mass and more advanced electronic components. This does not raise different questions of safety or effectiveness, safety was proved by compliance with respective standards AAMI/ANSI 60601-1 and IEC 60601-1-2.
Protection class	2	2	Same

	Applicant Device	Reference Device (Scheimpflug Imaging, Etc.)	Substantial Equivalence Comparison
Protection type	IP00	IP20	Different Under worst-case conditions (with the base unit set to maximum height). IP20 under normal conditions. For Pentacam OCT test was conducted in for the maximum height, This does not raise different questions of safety or effectiveness.
Device type	B	B	Same
Dimensions	305 x 259 - 404 x 512 - 542 mm (WxDxH)	278 x 320-400 x 502-532 mm (WxDxH)	Different Space for a larger number of components This does not raise different questions of safety or effectiveness.
Weight	27.8 kg	9 kg (only measuring head)	Different Weight of larger number of components. This does not raise different questions of safety or effectiveness

The Pentacam® Cornea OCT is as safe and effective as the predicate device Optovue SoliX OCT. The Pentacam® Cornea OCT has the same intended use and similar indications, technological characteristics, and principles of operation related to spectral-domain optical coherence tomography (OCT) imaging and measurement of corneal structures as the SoliX OCT.

Minor technological differences between the Pentacam® Cornea OCT and the predicate device do not raise new or different questions of safety or effectiveness. The Pentacam® Cornea OCT also incorporates Scheimpflug-based imaging and biometry functionalities that are consistent with those of the previously cleared Pentacam® AXL Wave, which is identified as a reference device. These functions do not alter the primary OCT-based imaging function.

Scientific information provided by the reference device Optovue SoliX, including the *Clinical Agreement and Precision Study of the Pentacam® Cornea OCT Compared to the Optovue SoliX*, supports the safety and effectiveness of the new technological characteristic of the Pentacam® Cornea OCT, namely the spectral-domain OCT scanning technology.

Bench and clinical testing demonstrate that the Pentacam® Cornea OCT is as safe and effective as its predicate device. Therefore, the Pentacam® Cornea OCT is substantially equivalent to the legally marketed predicate device.

This summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92. I certify that this summary is accurate and that it reflects the data in the premarket notification.