October 11, 2023

Heidelberg Engineering GmbH
℅ Lena Sattler
Consultant
Orasi Consulting, LLC.
226 1st Street
Bonita Springs, Florida 34134

Re: K230897
Trade/Device Name: Anterion
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: August 31, 2023
Received: August 31, 2023

Dear Lena Sattler:

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.

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K230897

Device Name
ANTERION

Indications for Use *(Describe)*
The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and measurement of the axial length.

The analysis covers:
- Cornea Thickness
- Anterior Segment
  - o Anterior chamber width, depth, volume and angle parameters
  - o Lens Thickness
- Axial Length

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Date Prepared October 10, 2023

SPONSOR/510(K) OWNER/ MANUFACTURER

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COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

ANTERION

CLASSIFICATION INFORMATION

Regulation Number:	21 CFR 886.1570
Classification name:	Ophthalmoscope
Device Class:	II
Common name:	Optical Coherence Tomography
Product Codes, Name:	OBO (Tomography, Optical Coherence)
Medical Specialty:	Ophthalmic
Classification Panel:	Ophthalmic Device Panel

PREDICATE DEVICE

ANTERION (K211817), Heidelberg Engineering GmbH

REFERENCE DEVICES

CIRRUS HD-OCT 5000 (K150977), Carl Zeiss Meditec Inc.

Pentacam AXL (K152311), Oculus Optikgerate GmbH

INDICATIONS FOR USE

The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and the measurement of the axial length.

The analysis covers:

- Cornea thickness
- Anterior segment
  - Anterior chamber width, depth, volume, and angle parameters
  - Lens thickness
- Axial Length

GENERAL DEVICE DESCRIPTION

The ANTERION is a diagnostic imaging device for the eye. The technology is based on swept-source optical coherence tomography (SS-OCT) technology. The device itself has two basic component groups:

- ANTERION Hardware (Imager/Base) with integrated forehead/ chin rest: The hardware includes imaging hardware (e.g., laser, LEDs, optics, detectors, hardware for spatial encoding) as well as a touch screen.

- ANTERION Software (V.1.2.4) (PC): The ANTERION Software includes the main user interface. The software allows for device control, such as selection of examination(s) and imaging parameter(s). The ANTERION software provides an interface for a Medical Image Management and Processing System.

The ANTERION hardware is separated in three parts: the Base (bottom part), the Imager (top part), and the Head Rest (forehead/chin rest).

For examinations, the patient places his/her head in the forehead/chin rest. The Head Rest is mechanically and electronically connected to the Base and controlled via a joystick. Placed within the stand are a stepper motor with additional mechanical parts

and a controller board, allowing the operator to move the motorized chin rest up or down for optimally positioning the patients' eye. An external fixation light is mounted at the forehead rest.

The Base mainly contains the power supply and PC connection of the device. In the Imager, the components for scanning, signal generation, and signal processing are contained.

The operator directly accesses two software modules, which are named AQM (acquisition module) and VWM (viewing module). The AQM allows selecting between examinations. The VWM shows acquired images, parameters, and reports.

The ANTERION device contains two imaging modalities, a scanning optical coherence tomography (OCT) modality and an infrared (IR) camera. The OCT modality allows for cross-sectional imaging and biometry, while the IR camera allows for en-face imaging of a patient's eye.

The ANTERION device provides four separate software applications (Apps) to acquire various imaging and measurements of the anterior segment of the eye: (1) the Imaging App (cleared under K211817), (2) the Cornea App, (3) the Cataract App and (4) the Metrics App. The Cornea App provides tomographic data and measurements paraments for the patient´s individual corneal geometry and corneal characteristics. The Cornea App provides tomographic data and parameters, such as corneal curvature and thickness. The Cataract App provides key measurements for the cataract surgery planning, such as corneal thickness, anterior chamber depth and axial length. The Metrics App generates OCT images and scan parameters for the anterior chamber such as anterior chamber angle and volume. The four ANTERION Apps are locked/unlocked independently by a license mechanism for each App. The software implementation of these Apps is realized within the AQM and VWM.
This submission is to seek clearance for the Metrics App, Cataract App and Cornea App.

To function as intended, the ANTERION must be connected to a Medical Image Management and Processing system (MIMPS) with compatible interface. To date, HEYEX 2 / HEYEX PACS is the only available MIMPS with compatible interface.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS BETWEEN THE SUBJECT AND THE PREDICATE DEVICE

The predicate ANTERION (K211817) and the subject ANTERION do not share identical technological characteristics. However, the differences in design are marginal and do not raise different questions of safety and effectiveness. The software of both devices, the predicate ANTERION (K211817) and the subject ANTERION, includes all available imaging functions (Imaging App, Cornea App, Cataract App, Metrics App) which are locked/ unlocked independently by a license mechanism for

each App. The main difference between both devices is that the predicate ANTERION (K211817) only provides the Imaging App to the customer, and the other Apps were not made available for the customer. For the subject ANTERION, all software Apps are available which expand the indications for use of the device and allow measurements regarding the anterior segment. Regarding the OCT specifications, the subject device additionally provides a lateral resolution of 45 µm which is specific for the Cornea App and therefore is not applicable for the predicate ANTERION. Only minor hardware changes regarding the assembling of the power supply, replacement of light sources and of the housing coating, were implemented for the subject device which have no impact on the technology and performance of the ANTERION.

	SUBJECT DEVICE ANTERION	**PREDICATE DEVICE ANTERION (K211817)**	**DISCUSSION**

Intended use/ Indications for use	The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization and measurement of the anterior segment and the measurement of the axial length.
	The analysis covers:
	• Cornea thickness
	• Anterior segment
	  ○ Anterior chamber width, depth, volume, and angle parameters
	  ○ Lens thickness
	• Axial Length
		The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization of the anterior segment.	Different: Predicate device is only for imaging of the anterior segment. The subject device provides automated measurements of corneal thickness, anterior chamber width, depth, and volume, anterior segment angle, lens thickness and vault, and axial length; the predicate device does not provide automated measurements of any anterior segment parameters.

Device classification name	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	Same
Main Technology	Swept Source OCT Technology	Swept Source OCT Technology	Same
Supporting Technologies	Infrared Camera	Infrared Camera	Same
OCT center wave length	1310 nm	1310 nm	Same
OCT axial resolution	<10 µm (tissue)	<10 µm (tissue)	Same
OCT lateral resolution	30 µm, 45 µm	30 µm	Similar: 45µm only for Cornea App
Scan length	5 – 16.5 mm	5 – 16.5 mm	Same

Number of A-Scans per B-Scan	256; 512; 768; 1024	256; 512; 768; 1024	Same
A-scan rate	50,000 Hz	50,000 Hz	Same
Number of B- Scans	1-65	1-65	Same
Scan Pattern	Line, Volume, Arc, Radial	Line, Volume, Arc, Radial	Same
Scan Center	Adjustable	Adjustable	Same
Tracking	Available	Available	Same
Number of averaged Scans	1; 2; 4; 8	1; 2; 4; 8	Same
IR camera image size (px)	768 x 576	768 x 576	Same
Dilation of pupil required?	No	No	Same
Eye contact required?	No	No	Same
Fixation light	Internal, external	Internal, external	Same
Working position	Upright sitting position of the patient, using chin rest	Upright sitting position of the patient, using chin rest	Same
User Interface	Joystick for user to move and align device, device has GUI (Graphical user interface) for display and analysis of data	Joystick for user to move and align device, device has GUI (Graphical user interface) for display and analysis of data	Same

NON-CLINICAL PERFORMANCE TESTING

Software documentation was provided, and software verification and validation was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and an overall risk assessment regarding security and safety of the device was conducted due to ISO 14971:2019.

Laser safety testing for the light sources used in ANTERION was provided and showed that the requirements according to FDA recognized standards IEC-60825-1:2007 and ANSI Z80.36:2016 were fulfilled.

Bench verification testing was conducted to demonstrate OCT spatial performance, device sensitivity, depth attenuation and performance of auxiliary functions. The device met all pre-determined acceptance criteria.

Biocompatibility of the device was demonstrated by cytotoxicity testing and chemical analysis according to ISO 10993-5:2009 and ISO 10993-18:2005, respectively, and supported by biocompatibility assessment according to 10993-1:2018.

Tests for electrical safety (ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012) and electromagnetic compatibility (IEC 60601-1- 2 Edition 4.0 2014-02) were performed with the ANTERION device and passed the relevant requirements of the applied standards.

Two prospective, observational clinical studies were conducted at a single clinical site in the United States to compare the clinical performance of the ANTERION Metrics App between the ANTERION and the CIRRUS HD-OCT 5000 devices (Protocol B-2018-3) and the clinical performance of the ANTERION Cataract and Metrics App between the ANTERION and the Pentacam AXL and a reading center (Protocol B-2018-5).

For Protocol B-2018-3, eligible participants age 22 or older were assigned to one of two sub-groups: 1) eyes with open angle (Group A), 2) eyes with narrow angle (Group B). Participants were excluded if they had active infection of inflammation in either eye, insufficient tear film or corneal reflex, rigid gas permeable (RGP) contact lens wear during the two weeks prior to the study visit, and/or soft CL wear within one hour of the study visit. A baseline eye examination that included manifest refraction, slit-lamp biomicroscopy, assessment of best-corrected visual acuity (BCVA), gonioscopy, tonometry, and cataract grading (where applicable) was performed to verify eligibility. One eye per participant was randomly selected as the study eye. Three ANTERION and three CIRRUS 5000 HD-OCT devices were used. These six instruments were paired with three operators to form three device-operator configurations. All participants were imaged repeatedly on all three configurations. Three replicates per acquisition type, per configuration were obtained from each participant. The order of imaging by configuration order, device order within configuration, and by acquisition type was randomized. Image quality was assessed by the operator after each acquisition. Manual correction of ANTERION segmentation and manual editing of the scleral spur and angle recess points were performed as needed. Image quality assessment of CIRRUS images was performed as consistent with the CIRRUS instructions for use. Repeatability and reproducibility of measurements was estimated using a two-way, random-effects analysis of variance (ANOVA) model. Agreement was characterized using Bland-Altman and Deming regression analyses.

30 participants were enrolled into Group A and 28 participants were enrolled into Group B. 29 Group A participants and 27 Group B participants completed the study. Data from 225 scans of 25 Group A participants and 234 scans of 27 Group B participants were included in precision analyses, respectively. Data from 27 Group A and 26 Group B participants were included in the agreement analyses, respectively. The mean age in the safety population was 45.6 ± 16.9 years overall (mean 37.1±12.7 years in Group A, 55.1±16.0 years in Group B). 68.4% (39/57) were women (60.0% [18/30] Group A, 77.8% [21/27] Group B). 44% (25/57) were Caucasian (50.0% [15/30] in Group A, 37.0% [10/27] in Group B), 21% (12/57) were Black/African American (16.7% [5/30] Group A, 25.9% [7/27] Group B), 22.8% (13/57) were Asian (30.0% [9/30] Group A, 14.8% [4/27] Group B). 28.1% (16/57) were Hispanic/Latino

(16.7% [5/30] Group A, 40.7% [11/27] Group B). Demographics are similar for the Precision Analysis Population and the Agreement Analysis Population. There were no adverse events related to this study. Manual segmentation/extension of ANTERION images was performed on 21.8% (59/271) of scans of open-angle study eyes and 74.5% (181/243) of scans of narrow-angle study eyes.

The following quantitative parameters were evaluated:

- Spur-to-Spur Distance
- Angle-to-Angle Distance
- Scleral Spur Angle 500/750 [°] (nasal and temporal)
- Angle Opening Distance 500/750 [µm] (nasal and temporal)
- Trabecular Iris Space Area 500/750 [mm^2] (nasal and temporal)
- Anterior Chamber Angle 500/750 [°] (nasal and temporal)
- Lens Vault

ANTERION precision results are presented in the tables below:

TABLE 1 B-2018-3 REPEATABILITY AND REPRODUCIBILITY OF ANTERION PRECISION ANALYSIS POPULATION OF OPEN ANGLE EYES

Eye Population Parameter	# of Subjects	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Eye(s) with open angle									
ACA 500 Nasal (°)	25	225	41.876	2.892	8.098	6.906	3.772	10.561	9.007
ACA 750 Nasal (°)	25	225	41.222	2.115	5.921	5.130	2.565	7.183	6.223
AOD 500 Nasal (mm)	25	225	0.561	0.048	0.135	8.584	0.067	0.188	11.945
AOD 750 Nasal (mm)	25	225	0.742	0.046	0.130	6.244	0.062	0.174	8.397
TISA 500 Nasal (mm^2)	25	225	0.195	0.017	0.047	8.665	0.022	0.063	11.463
TISA 750 Nasal (mm^2)	25	225	0.347	0.025	0.070	7.192	0.035	0.097	9.935
SSA 500 Nasal (°)	25	225	46.956	3.143	8.799	6.693	4.297	12.032	9.152
SSA 750 Nasal (°)	25	225	44.920	2.109	5.906	4.696	2.794	7.822	6.219
ACA 500 Temporal (°)	25	225	44.391	3.145	8.807	7.086	3.937	11.023	8.869
ACA 750 Temporal (°)	25	225	43.524	2.222	6.222	5.105	3.069	8.593	7.051
AOD 500 Temporal (mm)	25	225	0.588	0.062	0.173	10.523	0.087	0.245	14.856
AOD 750 Temporal (mm)	25	225	0.803	0.046	0.128	5.706	0.084	0.234	10.413
TISA 500 Temporal (mm^2)	25	225	0.201	0.021	0.060	10.622	0.032	0.089	15.746
TISA 750 Temporal (mm^2)	25	225	0.368	0.028	0.079	7.660	0.046	0.130	12.605
SSA 500 Temporal (°)	25	225	48.867	2.811	7.871	5.753	4.458	12.483	9.124
SSA 750 Temporal (°)	25	225	46.613	2.072	5.802	4.445	3.318	9.290	7.118
STS Distance (mm)	25	225	11.920	0.051	0.143	0.428	0.072	0.201	0.602
ATA Distance (mm)	25	225	12.009	0.060	0.167	0.497	0.065	0.181	0.539
Lens Vault (mm)	25	225	0.072	0.026	0.072	35.515	0.032	0.091	45.011

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.
ACA = Anterior Chamber Angle. AOD = Angle Opening Distance. TISA = Trabecular-Iris Space Area. SSA = Scleral Spur-Angle. STS Distance = Spur-to-Spur Distance. ATA Distance = Angle-to-Angle Distance.

TABLE 2 B-2018-3 REPEATABILITY AND REPRODUCIBILITY OF ANTERION PRECISION ANALYSIS POPULATION OF NARROW ANGLE EYES

Eye Population	# of	# of		Repeatability			Reproducibility		
Parameter	Subjects	Scans	Intercept	SD	Limit	CV%	SD	Limit	CV%
Eye(s) with narrow angle									
ACA 500 Nasal (°)	26	234	15.722	2.631	7.367	16.735	3.145	8.806	20.004
ACA 750 Nasal (°)	26	234	15.235	1.918	5.371	12.591	2.307	6.460	15.144
AOD 500 Nasal (mm)	26	234	0.164	0.024	0.068	14.870	0.033	0.092	19.965
AOD 750 Nasal (mm)	26	234	0.227	0.030	0.083	13.105	0.035	0.097	15.266
TISA 500 Nasal (mm²)	26	233	0.059	0.010	0.027	16.181	0.012	0.033	20.102
TISA 750 Nasal (mm²)	26	233	0.106	0.014	0.040	13.387	0.017	0.049	16.478
SSA 500 Nasal (°)	26	234	18.145	2.728	7.640	15.037	3.569	9.993	19.668
SSA 750 Nasal (°)	26	234	16.906	2.077	5.814	12.283	2.445	6.847	14.465
ACA 500 Temporal (°)	26	234	15.145	2.621	7.340	17.308	3.404	9.531	22.475
ACA 750 Temporal (°)	26	234	15.350	1.913	5.355	12.460	2.908	8.142	18.943
AOD 500 Temporal (mm)	26	234	0.152	0.028	0.078	18.363	0.037	0.104	24.415
AOD 750 Temporal (mm)	26	234	0.226	0.031	0.088	13.926	0.048	0.134	21.274
TISA 500 Temporal (mm²)	26	233	0.058	0.009	0.026	16.316	0.012	0.033	20.448
TISA 750 Temporal (mm²)	26	233	0.104	0.014	0.040	13.828	0.020	0.056	19.106
SSA 500 Temporal (°)	26	234	16.949	2.883	8.073	17.010	3.951	11.062	23.309
SSA 750 Temporal (°)	26	234	16.671	2.239	6.269	13.430	3.391	9.496	20.343
STS Distance (mm)	26	234	11.870	0.061	0.170	0.511	0.079	0.220	0.662
ATA Distance (mm)	26	234	11.994	0.085	0.237	0.706	0.095	0.267	0.795
Lens Vault (mm)	25	225	0.756	0.029	0.082	3.860	0.045	0.127	5.980

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.
ACA = Anterior Chamber Angle. AOD = Angle Opening Distance. TISA = Trabecular-Iris Space Area. SSA = Scleral Spur-Angle. STS Distance = Spur-to-Spur Distance. ATA Distance = Angle-to-Angle Distance.

For the second study B-2018-5, eligible participants age 22 or older were assigned to one of five sub-groups: 1) eyes with “normal anterior segment” (Group A), 2) eyes with cataract (Group B), 3) eyes with corneal abnormalities such as corneal ectasias (Group C), 4) eyes that were post-keratorefractive surgery (Group D), 5) pseudophakic/aphakic eyes (Group E). Exclusion criteria were similar to those described for Protocol B-2018-3. A baseline eye examination that included manifest refraction, slit-lamp biomicroscopy, assessment of best-corrected visual acuity (BCVA), tonometry, and cataract grading (where applicable) was performed to verify eligibility. One eye per participant was randomly selected as the study eye. Three ANTERION and three Pentacam AXL devices were used. These six instruments were paired with three operators to form three device-operator configurations. All participants were imaged repeatedly on all three configurations. Three replicates per acquisition type, per configuration were obtained from each participant. The order of imaging by configuration order, device order within configuration, and by acquisition type was randomized. Image quality was assessed by the operator after each acquisition. Manual correction of ANTERION segmentation was performed by an independent reading center and manual placement of the angle recess points were performed. Image quality assessment of Pentacam images was performed as consistent with the Pentacam’s instructions for use. Repeatability and reproducibility of measurements was estimated using a two-way, random-effects analysis of variance (ANOVA) model. Agreement was characterized using Bland-Altman and Deming regression analyses.

176 participants were enrolled and 172 completed the study. In the safety population, there were 27 in Group A, 33 in Group B, 45 in Group C, 29 in Group D, and 41 in Group E. The mean age was 52.6 ± 18.8 years (range 23 to 87 years). The mean age in Group A was 36.1±10.4 years (range 23 to 59); Group B, 66.9±6.8 years (range 48 to 80); Group C, 41.4±14.7 years (range 23 to 71); Group D, 43.1±13.9 years (range 24 to 72); Group E, 70.8±12.5 years (range 30 to 87). 65.1% (114/175) were women (55.6% [15/27] in Group A; 72.7% [24/33] in Group B; 57.8% [26/45] in Group C; 72.4% [21/29] in Group D; 68.3% [28/41] in Group E).

27.4% (48/175) of the safety population were Caucasian (44.4% [12/27] in Group A; 15.2% [5/33] in Group B; 26.7% [12/45] in Group C; 31.0% [9/29] in Group D; 24.4% [10/41] in Group E). 49.1% (86/175) were Black/African American (18.5% [5/27] Group A; 81.8% [27/33] Group B; 46.7% [21/45] Group C; 27.6% [8/29] Group D; 61.0% [25/41] Group E). 10.9% (19/175) were Asian (18.5% [5/27] Group A; 6.1% [2/33] Group B; 2.2% [1/45] Group C; 31.0% [9/29] Group D; 4.9% [2/41] Group E). 9.1% (16/175) were Native American/Alaskan Native (14.8% [4/27] Group A; 20.0% [9/45] Group C; 6.9% [2/29] Group D; 2.4% [1/41] Group E). 24.6% (43/175) were Hispanic/Latino (40.7% [11/27] Group A; 9.1% [3/33] Group

B; 33.3% [15/45] Group C; 24.1% [7/29] Group D; 17.1% [7/41] Group E). 95.1% (39/41) of Group E participants were pseudophakic and two Group E participants (4.9%) were aphakic. 67% (30/45) of Group B participants had nuclear sclerosis of grade 1.5+ or higher and 29% (13/45) had cortical cataracts. 69% (31/45) of Group C participants had keratoconus. 72% of Group D participants had prior laser-assisted in situ keratomileusis (LASIK) and the remainder had prior photorefractive keratectomy (PRK), radial keratotomy (RK), small-incision lenticular extraction, or corneal inlay implantation. Demographics are similar for the Precision Analysis Population and the Agreement Analysis Population. There were no adverse events related to this study. Manual segmentation correction/extension was performed in 2.9% (7/243), 10.1% (30/297), 11.6% (44/378), and 2.3% (6/261) of Metrics App scans for Groups A, B, C, and D, respectively. Manual segmentation correction was performed in 0.4% (1/243), 3.7% (11/297), 17.1% (64/375), 3.8% (10/261), and 3.5% (12/345) of Cataract App scans for Groups A, B, C, D, and E, respectively.

The following quantitative parameters were evaluated:

- Anterior Corneal Topography (3 mm ring and 6 mm zone)
- Posterior Corneal Topography (3 mm ring and 6 mm zone)
- Central Corneal Thickness (CCT) [µm]
- Thinnest Point Thickness [µm]
- Lens Thickness [mm]
- Anterior Chamber Depth [mm] (ANTERION Aqueous Depth plus CCT)
- Pupil Diameter [mm]
- White-to-White Distance [mm]
- Axial Length [mm]
- Anterior Chamber Volume [mm^3]

ANTERION precision results are presented in the tables below:

TABLE 3 B-2018-5 REPEATABILITY AND REPRODUCIBILITY OF ANTERION BIOMETRY MEASUREMENTS PRECISION ANALYSIS POPULATION OF NORMAL EYES

Parameter	# of Subjects	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Cataract App: Biometry									
Central corneal thickness [µm]	27	243	545.621	0.775	2.170	0.142	4.088	11.446	0.749
Thinnest point thickness [µm]	27	243	542.226	0.703	1.968	0.130	3.728	10.439	0.688
Anterior chamber depth [mm]	27	243	3.635	0.009	0.026	0.255	0.014	0.040	0.389
Axial length [mm]	27	243	24.513	0.004	0.012	0.018	0.006	0.018	0.027
Lens thickness [mm]	27	243	3.982	0.011	0.030	0.270	0.015	0.042	0.377
Metrics App: Biometry									
Central corneal thickness [µm]	27	243	546.679	1.106	3.096	0.202	4.181	11.706	0.765
Anterior chamber depth [mm]	27	243	3.636	0.009	0.024	0.239	0.013	0.037	0.362
Anterior chamber volume [mm³]	27	243	185.507	1.377	3.856	0.742	3.670	10.275	1.978
Lens thickness [mm]	27	243	3.988	0.010	0.027	0.239	0.015	0.041	0.371

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

TABLE 4 B-2018-5 REPEATABILITY AND REPRODUCIBILITY OF ANTERION BIOMETRY MEASUREMENTS PRECISION ANALYSIS POPULATION OF CATARACT EYES

Parameter	# of Subjects	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Cataract App: Biometry									
Central corneal thickness [µm]	33	297	527.694	2.351	6.584	0.446	4.321	12.100	0.819
Thinnest point thickness [µm]	33	297	522.104	0.672	1.881	0.129	3.412	9.554	0.654
Anterior chamber depth [mm]	33	297	3.128	0.011	0.030	0.337	0.016	0.045	0.512
Axial length [mm]	33	297	23.852	0.019	0.054	0.081	0.019	0.054	0.081
Lens thickness [mm]	33	295	4.661	0.012	0.034	0.262	0.015	0.042	0.325
Metrics App: Biometry									
Central corneal thickness [µm]	33	297	529.101	1.277	3.574	0.241	3.972	11.122	0.751
Anterior chamber depth [mm]	33	297	3.130	0.006	0.016	0.186	0.010	0.028	0.320
Anterior chamber volume [mm³]	33	295	132.199	0.821	2.298	0.621	1.548	4.335	1.171
Lens thickness [mm]	33	297	4.670	0.007	0.019	0.142	0.010	0.027	0.208

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

TABLE 5 B-2018-5 REPEATABILITY AND REPRODUCIBILITY OF ANTERION BIOMETRY MEASUREMENTS PRECISION ANALYSIS POPULATION OF EYES WITH CORNEAL ABNORMALITIES

Parameter	# of Subjects	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Cataract App: Biometry									
Central corneal thickness [µm]	43	363	495.294	1.872	5.243	0.378	4.367	12.227	0.882
Thinnest point thickness [µm]	43	363	470.957	4.023	11.263	0.854	5.116	14.325	1.086
Anterior chamber depth [mm]	43	363	3.746	0.014	0.039	0.370	0.019	0.052	0.498
Axial length [mm]	43	366	24.548	0.012	0.034	0.049	0.017	0.046	0.067
Lens thickness [mm]	40	337	4.001	0.016	0.045	0.399	0.018	0.051	0.457
Metrics App: Biometry									
Central corneal thickness [µm]	38	331	513.923	1.117	3.129	0.217	7.479	20.942	1.455
Anterior chamber depth [mm]	38	331	3.668	0.011	0.031	0.306	0.016	0.045	0.438
Anterior chamber volume [mm³]	39	339	187.635	1.124	3.148	0.599	2.669	7.472	1.422
Lens thickness [mm]	36	313	4.039	0.012	0.035	0.308	0.018	0.049	0.434

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

TABLE 6 B-2018-5 REPEATABILITY AND REPRODUCIBILITY OF ANTERION BIOMETRY MEASUREMENTS PRECISION ANALYSIS POPULATION OF POST-KERATOREFRACTIVE SURGERY EYES

Parameter	# of Subjects	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Cataract App: Biometry									
Central corneal thickness [µm]	29	261	479.893	1.076	3.012	0.224	4.637	12.984	0.966
Thinnest point thickness [µm]	29	261	473.157	1.224	3.427	0.259	4.394	12.304	0.929
Anterior chamber depth [mm]	29	261	3.568	0.008	0.024	0.236	0.012	0.033	0.328
Axial length [mm]	29	261	25.264	0.004	0.012	0.018	0.007	0.020	0.028
Lens thickness [mm]	29	260	4.110	0.009	0.024	0.209	0.013	0.037	0.322
Metrics App: Biometry									
Central corneal thickness [µm]	28	251	489.173	1.062	2.975	0.217	4.485	12.558	0.917
Anterior chamber depth [mm]	28	251	3.555	0.007	0.020	0.196	0.010	0.027	0.275
Anterior chamber volume [mm³]	28	251	177.715	1.203	3.368	0.677	2.477	6.935	1.394
Lens thickness [mm]	28	250	4.124	0.007	0.021	0.182	0.012	0.035	0.300

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

TABLE 7 B-2018-5 REPEATABILITY AND REPRODUCIBILITY OF ANTERION BIOMETRY MEASUREMENTS PRECISION ANALYSIS POPULATION OF EYES WITHOUT A CRYSTALLINE LENS

Parameter	# of Subjects	# of Scans	Intercept	Repeatability			Reproducibility		
				SD	Limit	CV%	SD	Limit	CV%
Cataract App: Biometry									
Central corneal thickness [µm]	39	345	539.041	0.800	2.241	0.148	3.420	9.576	0.634
Thinnest point thickness [µm]	39	345	533.188	0.753	2.110	0.141	3.015	8.443	0.566
Lens thickness [mm]	39	345	24.175	0.007	0.018	0.027	0.027	0.075	0.111
Metrics App: Biometry									
Central corneal thickness [µm]	40	358	540.115	1.202	3.365	0.223	3.413	9.555	0.632

All statistics are estimated (REML) from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Repeatability limit = 2.8 × Repeatability SD. Repeatability CV% = (Repeatability SD)/Intercept × 100%.
Reproducibility limit = 2.8 × Reproducibility SD. Reproducibility CV% = (Reproducibility SD)/Intercept × 100%.

CONCLUSION

ANTERION (with software version 1.2.4) has the same intended use as the legally marketed predicate device identified in this 510(k) notification. The Indications for Use (IFU) statement differs from those of the predicate device, but these differences do not change the intended use of the device. The technological characteristics of the ANTERION V1.2.4 differ from those of the predicate device, however, the differences do not raise new or different questions of safety or effectiveness. Results of the non-clinical performance testing demonstrate that the ANTERION V1.2.4 functions as intended. Results of the clinical performance testing demonstrate a favorable clinical performance profile that supports a determination of substantial equivalence. The non-clinical and clinical performance testing demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate.