November 5, 2021

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

Re: K211817
Trade/Device Name: Anterion
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: September 24, 2021
Received: September 27, 2021

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K211817

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 of the anterior segment.

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 June 10, 2021

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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

Visante OCT (K051789), Carl Zeiss Meditec Inc.

REFERENCE DEVICE

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

INDICATIONS FOR USE

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

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/Basis) 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 (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 PC software additionally stores, receives, and displays the acquired data.

The ANTERION hardware is separated in three parts: the Basis (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 Basis 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 Basis 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, while the IR camera allows for en-face imaging of a patient's eye.

The Imaging App, the subject of this submission, is the foundation of the ANTERION platform, and focuses on the high-resolution visualization of the entire anterior segment, from the anterior surface of the cornea to the posterior surface of the lens.

The Imaging App delivers swept-source OCT images that allow visualization of anterior segment pathologies and evidence of surgical interventions, e.g. keratoplasty, LASIK, implanted IOLs, and phakic lenses.

SUBSTANTIAL EQUIVALENCE

The Substantial Equivalence Summary tables below illustrate the comparisons of the ANTERION to the predicate device and the reference device.

The imaging function of the ANTERION is similar to the anterior imaging function of the predicate device Visante OCT (K051789) and the reference device CIRRUS HD-OCT 5000 (K150977) in intended use and technological characteristics.

INTENDED USE/INDICATIONS FOR USE STATEMENT CHART

SUBJECT DEVICE ANTERION	PREDICATE DEVICE Visante OCT (K051789)	REFERENCE DEVICE CIRRUS HD-OCT 5000 (K150977)	Discussion
The ANTERION is a non-contact ophthalmic imaging and analysis device for the eye. It is intended for visualization of the anterior segment.	The Visante™ OCT is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging and measurement of ocular structures in the anterior segment, such as corneal and LASIK flap thickness.	The CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures. The device is indicated for visualizing and measuring anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The CIRRUS normative databases are quantitative tools indicated for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of normal subjects. The CIRRUS OCT Angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid. The CIRRUS HD-OCT is indicated as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.	Similar. All devices support imaging of the anterior segment of the eye.

TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

(*specific data for the Anterior Segment module of CIRRUS HD-OCT 5000)

	SUBJECT DEVICE ANTERION	**PREDICATE DEVICE Visante OCT (K051789)**	**REFERENCE DEVICE CIRRUS HD-OCT 5000 (K150977)**	**Discussion**
Device classification name	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	Same
Main Technology	Swept Source OCT Technology	Time Domain OCT Technology	Spectral Domain OCT Technology	The OCT technologies are different, but the resulting images show comparable structures
Supporting Technologies	Infrared Camera	Video camera	Infrared Camera	Similar. Their main usage is to support a proper OCT acquisition.
OCT center wave length	1310 nm	1310 nm	750 nm	Similar. The OCT wavelength of the ANTERION and Visante OCT are intended for anterior segment imaging. The CIRRUS HD-OCT 5000 is optimized for posterior segment imaging but can also be used to create anterior segment

	SUBJECT DEVICE ANTERION	PREDICATE DEVICE Visante OCT (K051789)	REFERENCE DEVICE CIRRUS HD-OCT 5000 (K150977)	Discussion
				images using a special lens module.
OCT axial resolution	<10 µm (tissue)	18 µm (in tissue)	5 µm (in tissue)	Similar
OCT lateral resolution	30 µm	60 µm	20 µm – 45 µm*	Similar
Scan length	5 – 16.5 mm	10 mm – 16 mm	9 mm - 15.5 mm*	Similar
Scan depth (in tissue)	8 mm	3 mm; 6 mm	2 mm; 2.9 mm; 5.8 mm*	The ANTERION provides images showing the full anterior segment including the posterior lens.
Number of A-Scans per B-Scan	256; 512; 768; 1024	128; 256; 512	1024; 2048*	Similar
A-scan rate	50,000 Hz	2,000 Hz	27,000/68,000 Hz	The OCT technology used in the Visante cannot provide high A-Scan rates
Number of B-Scans	1-65	1; 2; 3; 4; 8; 16	1-24*	Adjustable in all devices.
Scan Pattern	Line, Volume, Arc, Radial	Line, Line Raster Scan	Line, Line Raster Scan, Radial	Similar
Scan Center	Adjustable	Not adjustable	Not adjustable	The ANTERION provides more flexibility in defining the scanned area.

	SUBJECT DEVICE ANTERION	PREDICATE DEVICE Visante OCT (K051789)	REFERENCE DEVICE CIRRUS HD-OCT 5000 (K150977)	Discussion
Tracking	Available	Available	Not available for anterior segment imaging	Tracking improves the ability to correlate acquired B-Scans to each other and enables scanning of larger areas.
Number of averaged Scans per B-Scan/	1; 2; 4; 8	1; 4	20*	All devices provide some sort of scan averaging.
IR camera image size (px)	768 x 576	No information found	1280 x 1024	Differences in the camera specifications are not relevant
Patient/ User Interface				
Patient groups	No restrictions regarding patient groups	No restrictions regarding patient groups	No restrictions regarding patient groups	Same
Dilation of pupil required?	No	No	No	Same
Eye contact required?	No	No	No	Same
Fixation light	Internal, external	Internal, external	Internal, external	Same
Working position	Upright sitting position of the patient, using chin rest and forehead rest	Upright sitting position of the patient, using chin rest and forehead rest	Upright sitting position of the patient, using chin rest and forehead rest	Same
User Interface	Joystick for user to move and align device, device has GUI (Graphical user interface) for display and analysis of data	Graphical user interface for user to move and align device, device has GUI for display and analysis of data	Graphical user interface for user to move and align device, device has GUI for display and analysis of data	All systems provide a display attached to the device, showing a GUI to supervise and

	SUBJECT DEVICE ANTERION	PREDICATE DEVICE Visante OCT (K051789)	REFERENCE DEVICE CIRRUS HD-OCT 5000 (K150977)	Discussion
				control the acquisition and analyze the data.

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NON-CLINICAL PERFORMANCE SUMMARY

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 14971:2007.

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.

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 radiation (EC 60601-1-2 Edition 4.0 2014-02) were performed with the Anterion device and passed the relevant requirements of the applied standards.

CLINICAL EVALUATION

A prospective, clinical study was conducted at a single clinical site in the United States to compare the clinical performance of the ANTERION Imaging App between the ANTERION and the CIRRUS HD-OCT 5000 devices. 87 participants age 22 or older meeting eligibility criteria in at least one eye were enrolled into two study cohorts, the "Normal Anterior Segment group" (without abnormality present in the anterior segment of the eye) and the "Abnormal Anterior Segment group" (those anterior segment abnormalities identified with the slit lamp exam such as glaucoma and corneal surgeries). One eye of each subject was selected to be the study eye, (randomly determined when both eyes were eligible).

The following endpoints were evaluated:

- The image quality grade of the acquired images.
- Agreement in identification of abnormality between the B-Scan images using the slit lamp examination as the reference.

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An eye examination was performed to determine study eligibility, then inclusion and exclusion criteria were assessed. The anterior segment abnormalities and a primary Abnormality of Interest (AOI) were identified during the eye examination by the investigator (when applicable). The device order and the acquisition type order was randomized.

Imaging was performed by the site operators based on randomization

The first acceptable scans were sent to the Reading Center for grading. Each grader graded each image for image quality and for identification and assessment of abnormality (if applicable). The images were presented to three independent graders, who were blinded to the subject identification, population allocation, eye examination results and to each other's grading results. Majority rule was applied to get consensus. For each device and acquisition type (if applicable), three qualified graders graded the OCT images for quality into categorical groups (1 = poor, 2 = fair, 3 = good).

In each image the visibility of following structures was assessed:

- Cornea/Conjunctiva
- Iris (temporal/nasal)
- Anterior Lens Surface
- Scleral Spur (temporal/nasal)
- Angles (temporal/nasal)

The graders also graded for presence or absence of pre-defined key abnormalities, specified on the grading form.

Eighty-seven subjects were enrolled in this study. Thirty-four in the Normal Anterior Segment population and fifty-three in the Abnormal Anterior Segment population.

The mean age was 45.7 ± 16.1 years overall, with the Abnormal Anterior Segment population subjects being older. The study population gender distribution was 67.9% male and 32.1% female. Sixty-seven percent (67%) were not Hispanic or Latino, 34% were Caucasian and 42% African American. The study eyes were fairly equally distributed between right and left eyes (51% right, 49% left).

To compare the image quality of the ANTERION and the CIRRUS devices, key anatomical structures were evaluated for image quality (Good/Fair/Poor) by the independent Reading Center by three masked graders.

Figure 1 below summarizes the structure image quality for all study eyes of the effectiveness analysis population. Overall, the ANTERION shows superiority in image quality compared to each of the three CIRRUS scans.

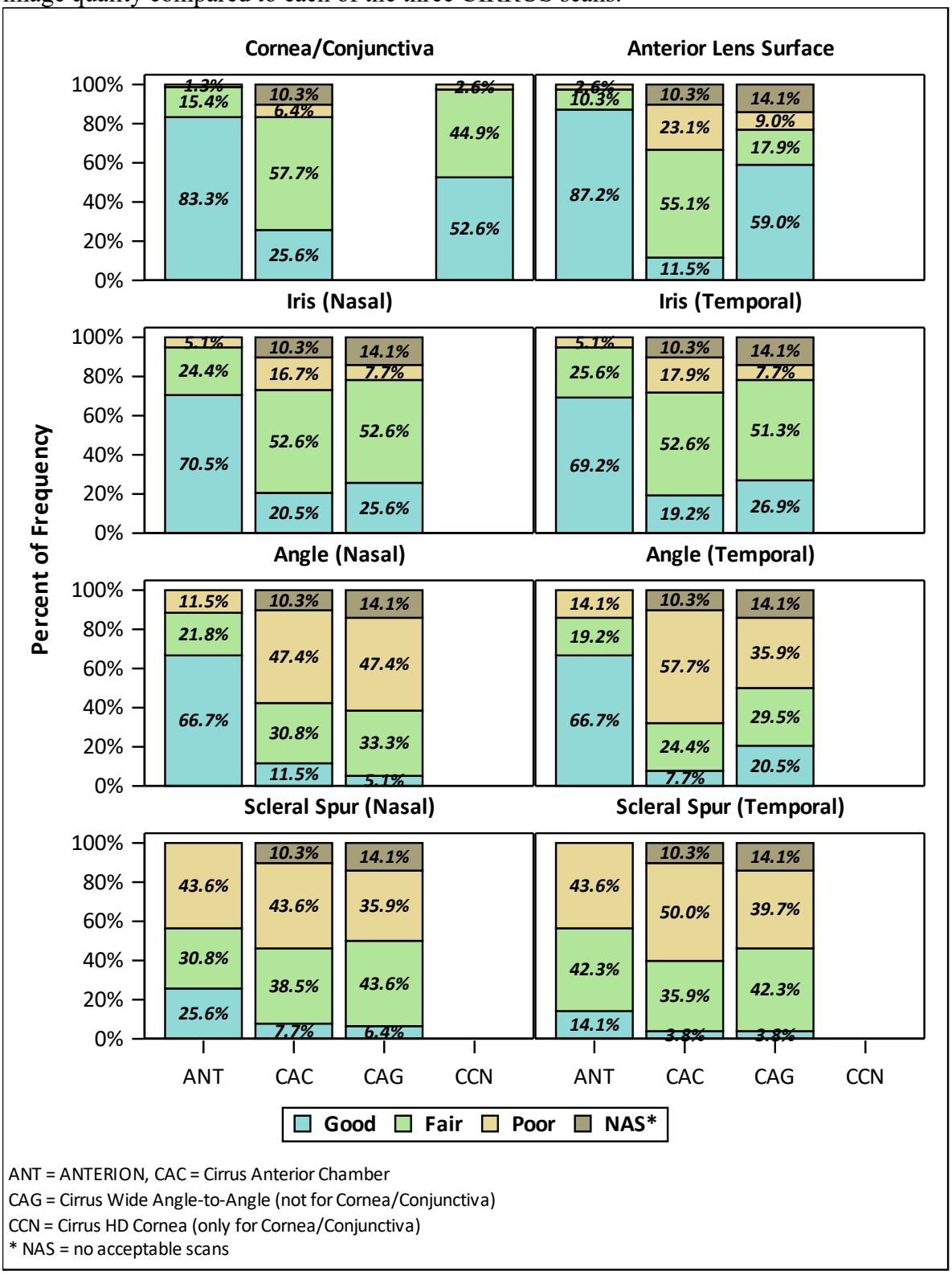
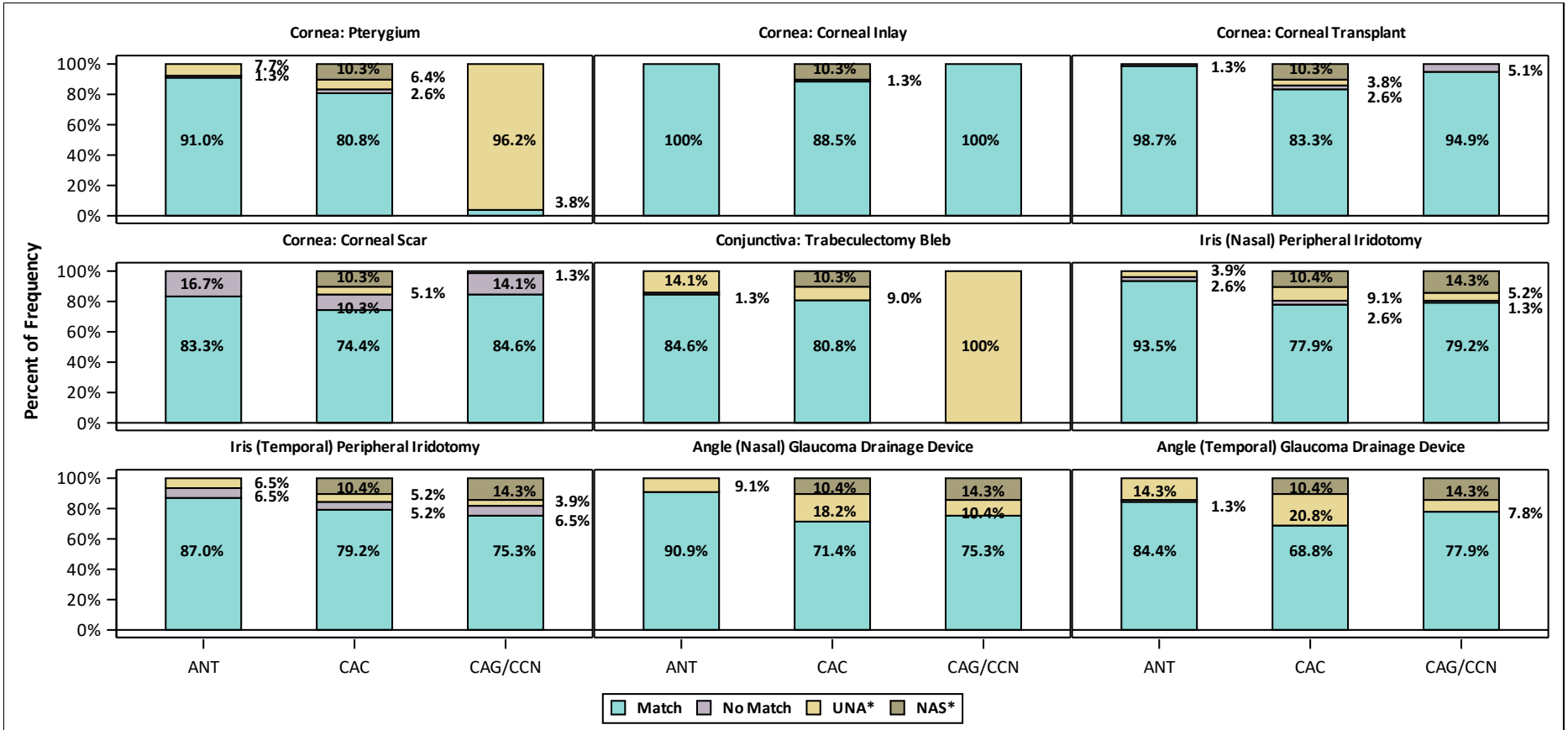


FIGURE 1: IMAGE QUALITY OF EACH STRUCTURE BY DEVICE AND SCAN TYPE

The slit lamp examination, as well as the OCT imaging as assessed by the Reading Center, have been assessed for the presence or absence of the predefined abnormalities. Figure 2 below illustrated the comparison among the different OCT scan types, using the slit lamp results as the reference. Overall, the ANTERION shows superiority compared to each of the three CIRRUS scans in identifying the abnormality in reference with the slit lamp examination.



ANT = ANTERION, CAC = Cirrus Anterior Chamber, CAG = Cirrus Wide Angle-to-Angle (not for Cornea/Conjunctiva), CCN = Cirrus HD Cornea (only for Cornea/Conjunctiva)
Match = abnormality is identified both present or both absence in Slit Lamp examination and the OCT scan.
No Match = abnormality is identified differently in Slit Lamp examination and the OCT scan (i.e., one present and one absence).
* UNA = unable to assess, NAS = no acceptable scans
IMG-073 was excluded from the summary of Iris and Angle due to the slit lamp assessment of Unable Assess because of other abnormality.

FIGURE 2: OCT ABNORMALITY IDENTIFICATION USING SLIT LAMP IDENTIFICATION AS REFERENCE BY DEVICE AND SCAN TYPE

There were no adverse event occurring during the course of the study.

The results of this study illustrated that when using OCT to visualize the anterior segment, ANTERION's overall OCT image quality and ability to visualize key anatomical structures on OCT images was similar to or better than CIRRUS for all scan patterns and all subject populations. Furthermore, using the slit lamp examination as a reference, the results indicate that ANTERION offers an equal or superior ability in identifying each pre-specified abnormality as compared to CIRRUS. Therefore, the study results support substantial equivalence of ANTERION and the CIRRUS 5000 with Anterior Segment Premier Module in regard to image quality, the ability to discern key anatomical structures, and the ability to identify various anterior segment abnormalities.

CONCLUSION

Comparison of intended use, technological characteristics, and clinical performance data as well as evaluation of non-clinical testing support substantial equivalence of the ANTERION subject device to the predicate and reference devices.