November 9 ,2022

Optovue, Inc.
Robert Lundberg
VP Regulatory/Quality
2800 Bayview Drive
Fremont, California 94538

Re: K222166
    Trade/Device Name: Solix
    Regulation Number: 21 CFR 886.1570
    Regulation Name: Ophthalmoscope
    Regulatory Class: Class II
    Product Code: OBO, HKI
    Dated: September 30, 2022
    Received: October 3, 2022

Dear Robert Lundberg:

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 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

Indications for Use

510(k) Number *(if known)*

K222166

Device Name
SOLIX™

Indications for Use *(Describe)*

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. 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.

The non-mydriatic color fundus camera of SOLIX™ is an integrated non-contact, high resolution digital imaging component which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. The SOLIX™ fundus camera component is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

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.

510(k) Summary

Submitter Information

Company	Optovue, Inc. 2800 Bayview Drive Fremont, CA 94538
Contact Person	Robert Lundberg VP Regulatory/Quality Tel: (951) 741-2776 Email: b.lundberg@visionix.com
Date Prepared	07 November 2022

Device Information

Device Trade Name	SOLIX™
Device Common Name	Optical Coherence Tomography
Classification Regulation	21 CFR 886.1570
Classification Name	Ophthalmoscope
Device Class	Class II
Device Regulation Panel	Ophthalmic
Product Code	OBO, HKI

Predicate/Reference Devices

Primary Predicate:	K180660: Avanti, cleared on June 8, 2018
Secondary Predicate:	K122572: iCam Fundus Camera, cleared on January 11, 2013

Indications for Use

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. 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.

The non-mydriatic color fundus camera of SOLIX, is an integrated non-contact, high resolution digital imaging component which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. The SOLIX fundus camera component is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

Device Description

SOLIX is a computer-controlled, ophthalmic imaging system with combined spectral-domain optical coherence tomography (SD-OCT) and non-mydriatic, digital fundus camera. The SD-OCT employs non-invasive, non-contact, low coherence interferometry to acquire cross-sectional tomograms of the anterior and posterior segment of the eye and motion-contrast images of the retinal microvasculature (i.e., OCT "angiography" [OCTA]). The fundus camera produces color internal and external ocular images.

Substantial Equivalence
SOLIX vs Avanti

Device	SOLIX (Proposed Device)	Predicate Devices Primary Predicate Avanti	Substantial Equivalence Comparison
510(k) Number & Classification	K222166 Class II	K180660 Class II	
Date of Clearance	TBD	June 8, 2018	
Trade Name	SOLIX	Avanti	
Manufacturer	Optovue, Inc.	Optovue, Inc.	
Indications For Use	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. 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.	The Avanti 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 epithelia, corneal stroma, pachymetry, corneal power, and anterior chamber of the eye. With the integrated normative database, Avanti is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of a known normal subjects. It is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases. The Avanti 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.	Same
Technological Characteristics	Spectral-Domain Optical Coherence Tomography (SD-OCT)	Spectral-Domain Optical Coherence Tomography (SD-OCT)	Same
System Components	• 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	• Scanner • Control Unit • Chin and Head rest • Joystick and base assembly • Computer with Windows operating system • Monitor • Keyboard and Mouse • System Table • CAM Lens	Same
Signal Type	Optical scattering from tissue for OCT	Optical scattering from tissue for OCT	Same

Device	SOLIX (Proposed Device)	Predicate Devices	Substantial Equivalence Comparison
		Primary Predicate Avanti	
OCT Light Source	Superluminescent diode (SLD) 840nm	Superluminescent diode (SLD) 840nm	Same
OCT Optical Power	1.45mW (at cornea)	0.75mW (at cornea)	SLD power in SOLIX is increased from 0.75mW to 1.45mW to compensate the loss of photon energy due to higher scanner speed. With higher power, it achieves similar level of Signal to Noise Ratio (SNR) as Avanti.
OCT Optical Power	1.45mW (at cornea)	0.75mW (at cornea)	The light exposure safety issue in SOLIX is analyzed in Dr. David Sliney's report. The near- infrared radiation from an SLD in SOLIX is below all of the applicable exposure limits -including the guidelines for ophthalmic instrument exposure.
Fixation Light Source	Blue LED	Blue LED	Same
IR Fundus Imaging Light Source	NIR LED	NIR LED	Same
Iris Viewer Illumination	IR LED	N/A	Iris imaging is added for external visualization to facilitate patient alignment. No impact on the systems' essential functions – OCT.
Working Distance	Retina imaging: 35 mm With CAM (Cornea Anterior Module) attached: 20mm	Retina imaging: 22 mm With CAM (Cornea Anterior Module) attached: 13mm	The longer working distance in SOLIX improves the system's usability.
Ergonomic	• Chin and forehead rest • Joystick for alignment on the eye	• 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)	5µm	5µm	Same
Scan Rate	120,000 A-Scan/second	70,000 A-Scan/second	The OCT scan speed increased from 70Khz to 120Khz with a faster line scan camera from same vendor.
Scan Depth	~up to 3 mm except full- range scans up to 6.25 mm such as FullRange™ Retina and FullRange™ AC scans	~up to 3mm	Full-range technology is introduced to increase scan depth for two specific scans only.
AngioVue (wider FOV)	AngioVue 12mm	N/A	With faster scan speed, SOLIX offers AngioVue scan with wider field of view: Scan area: 12mm x12mm and Sampling Density 600x600

Device	SOLIX (Proposed Device)	Predicate Devices	Substantial Equivalence Comparison
		Primary Predicate Avanti	
AngioVue (wider FOV)	AngioVue 9mm	N/A	With faster scan speed, SOLIX offers AngioVue scan with wider field of view: Scan area: 9mm x9mm and Sampling Density 600x600
AngioVue	AngioVue Retina	HD Angio Retina 6.0mm	SOLIX scan area: 6.4mmx6.4mm; Increase sampling density from 400 x400 (Avanti) to 512x512 (SOLIX)
AngioVue	AngioVue 3mm	Angio Retina 3.0mm	Same Scan Area: 3mmx3mm; Increase sampling density from 304x304 (Avanti) to 400x400 (SOLIX)
AngioVue	AngioVue Disc	HD Angio Disc 4.5mm	Same scan area: 6x6mm; Increase sampling density from 400x400 (Avanti) to 512x512 (SOLIX)
Retina	Line	Line	Similar. Adjustability: Length 6-12 mm (SOLIX) vs 2-12mm(Avanti)
Retina	FullRange Retina	N/A	Essentially it is an enhanced line scan. Scan Depth is 6.25mm
Retina	Retina Cube	3D Retina	Same scan Area: 6.4x6.4mm; Retina Cube: Sampling Density 512x200; 3D Retina: Sampling Density 385x141;
Retina	Raster	Raster	Similar. Adjustability: Height 2-10 mm(SOLIX) vs 1-8mm(Avanti)
Retina	Radial lines	Radial lines	SOLIX: 1024x12, Scan Length: 6-12mm; Avanti: 1024x18, Scan Length: 2-12mm;
Nerve Fiber	Disc Cube	3D Disc	Same scan area: 6x6mm; Disc Cube: Sampling Density 350x350; 3D Disc: Sampling Density 513x101
Retina	Wellness	N/A	Scan Area:12x9 mm; Sampling Density: 600x130
Cornea	Corneal Map	Pachymetry Pachymetry Wide	Same radial scan pattern. Scan length: Corneal Map 10mm vs Pachymetry 6mm and Pachymetry Wide 9mm
Cornea	Anterior Radial	Cornea Cross Line	Same type of meridian scans. Increased # of meridians from 2 (Avanti) to 16 (SOLIX)
Cornea	Cornea Line	Corneal Line	Similar. 1700 A-Scans/line (SOLIX) vs 1020 A-Scans/Line (Avanti)
Cornea	Cornea Angle	Angle	Same
Cornea	Cornea Cube	3D Cornea	Similar cube scan pattern. Increase sampling density from 513x101 (Avanti) to 513x256 (SOLIX)

Device	SOLIX (Proposed Device)	Predicate Devices	Substantial Equivalence Comparison
		Primary Predicate Avanti	
Cornea	FullRange AC	N/A	Essentially it is an enhanced line scan. Scan Depth is 6.25mm
Motion Artifacts Reduction	Tracking based on IR fundus image + MCT	Tracking based on IR fundus image + MCT	Same
Post- Processing for OCT Scans	• 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	• 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	Substantial Equivalence: The results are substantial equivalent as verified by clinical study data. SOLIX's PAR is updated to further reduce the projection artifacts, as evidenced by the qualitative assessment of clinical study data. SOLIX's vessel extraction method is updated to extract vessels in the relatively low OCTA signal areas, as evidenced by the bench (phantom) and clinical studies.
Post-Processing for OCT Scans	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	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	Same
Reference Database (RDB)	OCT structural RDB Collected for the following scans: AngioVue Retina, AngioVue Disc, Retina Cube Disc Cube and Wellness scans • No OCT Angiography RDB available	• Avanti RDB for OCT scans, including Retinal Map scan, GCC scan, and ONH scan • No OCT Angiography RDB available	Same as predicate device, SOLIX only offers OCT structural RDB based on different types of cube scans. SOLIX's RDB provides additional colors when the confidence intervals of quantile limits are overlapped.
Device Packaging and Sterilization	The device is not sterile, does not require sterilization, and does not include shelf-life claims on product labeling.	The device is not sterile, does not require sterilization, and does not include shelf-life claims on product labeling.	Same
	The device is not sterile and does not require sterilization. Shipping packaging has been designed to safely transport the device to the end user facility.	The device is not sterile and does not require sterilization. Shipping packaging has been designed to safely transport the device to the end user facility.	Same

SOLIX vs iCam

Device	SOLIX (Proposed Device)	Predicate Devices Secondary Predicate iCam	Substantial Equivalence Comparison
510(k) Number & Classification	**TBD** **Class II**	**K122572** **Class II**	
Date of Clearance	**TBD**	**January 11, 2013**	
Trade Name	**SOLIX**	**iCam**	
Manufacturer	**Optovue, Inc.**	**Optovue, Inc.**	
Indications For Use	The non-mydriatic color fundus camera of SOLIX, is an integrated non-contact, high resolution digital imaging component which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. The SOLIX fundus camera component is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.	The iCam is a non- contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non- mydriatic conditions. iCam is indicated for in- vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health. iCam provides images only and does not provide any diagnostic, pathological analysis or classification of ocular health or disease.	Same
Technological Characteristics	Color fundus imaging	Color fundus imaging	Same
System Components	• Retina illumination Optics path. • Retina image optics path • Retina Camera	• Retina illumination Optics path. • Retina image optics path • Retina Camera	Same
Signal Type	Photography under white light flash	Photography under white light flash	Same
Flash light source for photographing	White LED	White LED	Same
IR Fundus Imaging Light Source	NIR LED	NIR LED	Same
Splitbar Illumination	NIR LED	NIR LED	Same
Working Distance Indicator (WDI) Illumination	NIR LED	NIR LED	Same
Iris Viewer Illumination	IR LED	N/A	Iris imaging is added for external visualization to facilitate patient alignment. No impact on the systems' essential functions – Color Fundus Photography.
Working Distance	Retina imaging: 35 mm With CAM (Cornea Anterior Module) attached: 20mm	Retina imaging: 25mm	The longer working distance in SOLIX improves the system's usability.
Ergonomic	• Chin and forehead rest • Joystick for alignment on the eye	• Chin and forehead rest • Joystick for alignment on the eye	Same

Device	SOLIX (Proposed Device)	Predicate Devices	Substantial Equivalence Comparison
		Secondary Predicate iCam	
Pupil Diameter (Non-Mydriatic fundus imaging)	≥4.0mm ≥3.3mm (small pupil mode)	≥4.0mm	Smaller light ring mode is added to deliver more light into the eyes with small pupils. The general design principle is similar for normal and small pupil modes.
Field of View (Color Fundus Imaging)	45° 35° (small pupil mode)	45°	Smaller light ring mode is added to deliver more light into the eyes with small pupils. The general design principle is similar for normal and small pupil modes. In small pupil mode, the FOV is a tradeoff with small pupil mode.
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
Photo	Fundus Photo	Color Fundus	Similar. Small pupil mode added in SOLIX
Photo	Disc Photo	Color Fundus	Similar. Small pupil mode added in SOLIX
Photo	Exterior Color	External Image	Same
Photo	External IR	N/A	940nm IR Illumination to visualize external structure
Device Packaging and Sterilization	The device is not sterile, does not require sterilization, and does not include shelf-life claims on product labeling.	The device is not sterile, does not require sterilization, and does not include shelf-life claims on product labeling.	Same
	The device is not sterile and does not require sterilization. Shipping packaging has been designed to safely transport the device to the end user facility.	The device is not sterile and does not require sterilization. Shipping packaging has been designed to safely transport the device to the end user facility.	Same

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE SUBJECT DEVICE AND PREDICATE DEVICE

The main comparison for the determination of substantial equivalence is between SOLIX and Avanti. The SOLIX and Avanti do not share identical technological characteristics. However, these differences do not raise different questions of safety and effectiveness.

SOLIX has the following OCT differences from the predicate, Avanti:

OCT hardware
- The SOLIX OCT scan speed increased from 70kHz to 120kHz with a faster line scan camera.
- The power of the SOLIX light source (superluminescent diode [SLD] with 840 nm central wavelength and FWHM of 50 nm) is increased from 750 mW to 1.45 mW to compensate for the loss of photon energy due to the higher scanning speed. With higher power, it achieves similar level of Signal to Noise Ratio (SNR) as Avanti.
- The line-scan camera-based SOLIX spectrometer was changed from an infrared charge-coupled device (CCD) camera sensor to a color complementary metal-oxide semiconductor (CMOS) sensor.
- The SOLIX reference arm modified with a new "phase galvo module" to allow for an increased scan depth to 6.25 mm in the FullRange Retina and FullRange AC scans.
- The field of view (FOV) of the optical path for color fundus images and for OCT scan tracking/macula visualization was changed from 35° to 45°. The new color fundus image path is similar to that of the iCam.
- An external eye image path (for iris images) was added to guide patient alignment and to allow for acquisition of infrared images of the external area of the eye.

OCT software
- The SOLIX algorithm for OCTA-based vessel density (VD) parameters includes improved projection artifact removal (PAR), improved detection of vessels with low OCT signal, and improved accuracy of the binary vessel mask. The vessel extraction algorithm in SOLIX uses a local thresholding method applied to the OCTA image partitioned into sub-regions, while the Avanti vessel extraction algorithm uses a global thresholding method that is applied to the entire OCTA image without any partitioning.
- The default Bruch's membrane opening (BMO) plane elevation for the calculation of the cup dimensions (AngioDisc and Disc Cube scans) is 150 µm instead of zero.
- SOLIX has two additional, wider-field AngioVue scans (9×9 mm and 12×12 mm).
- The SOLIX 3×3-mm and 6.4×6.4-mm AngioVue Retina scan and 6.0×6.0-mm AngioVue Disc scan have higher scan density (400 A-scans × 400 B-scans vs. 304 A-scans × 304 B-scans; 512 A-scans × 512 B-scans vs. 400 A-scans × 400 B-scans, respectively); increased scan density for Retina Cube and Disc Cube scans.

- The SOLIX cornea map size increased from 9 mm to 10 mm in diameter.
- New SOLIX scan pattern, the 12×9-mm Wellness scan.
- New SOLIX reference database (RDB) for certain structural quantitative parameters measured on five scan patterns (AngioVue Retina, AngioVue Disc, Retina Cube, Disc Cube, and Wellness scans).

Performance Testing

The following non-clinical and clinical performance testing were provided in support of the substantial equivalence determination.

Non-clinical Performance Testing

The following non-clinical bench tests were performed including,
- Spatial Performance
- Sensitivity
- OCT Angiography: A set of 3D digital phantoms with known vessel density ground truth was designed to determine the accuracy of SOLIX device software for vessel density measurement from AngioVue Retina and AngioVue Disc scans. A similar set of phantoms was created to determine vessel density accuracy of the Avanti predicate device software for comparison to SOLIX accuracy. Improved accuracy was observed from SOLIX vessel density measurements.
- Auxiliary Functions
- Testing to the standards
  - Safety and Essential Performance: AAMI/ANSI ES60601-1
  - Electromagnetic Compatibility: IEC 60601-1-2
  - Usability: IEC 60601-1-6
  - Biocompatibility: ISO 10993-1, ISO 10993-5, ISO 10993-10
  - Ophthalmic Instruments & Light Hazard Protection: ISO 15004-1, ISO 15004-2
- Light Hazard Protection for Ophthalmic Instruments: ANSI Z80.36-2016
- Software Verification and Validation Testing: Device software was verified and validated to support the indications for use according to BS EN 62304:2006 Medical Device Software - Software life cycle processes and FDA's General Principles of Software Validation; Final Guidance for Industry and FDA Staff. In accordance with the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005," documentation provided demonstrates that the software performed as intended, met acceptance criteria, overall product safety, and patient safety.

The software for this device is determined to be a "moderate" level of concern, since a malfunction of, or a latent design flaw in the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury. There was no change in the level of concern from the proposed SOLIX and its predicates Avanti and iCam devices.

Clinical Performance Testing

Clinical studies were conducted according to BS EN ISO 14155:2011, *Clinical investigation of medical devices for human subjects - Good clinical practice*, and 21 CFR 50 and 21 CFR 56 to demonstrate substantial equivalence of the subject SOLIX device to the predicate Avanti and iCam devices.
Two clinical studies were conducted to evaluate the following:

1) Estimation of repeatability and reproducibility of the SOLIX in measuring posterior and anterior segment quantitative parameters;
2) Comparison of image quality in fundus photographs from SOLIX and from the predicate, iCAM.

An additional clinical study was conducted to generate a reference database (RDB) for structural quantitative parameters derived from five SOLIX scan patterns and a cohort of individuals without significant ocular pathology.

Solix OCT Performance – Anterior Segment

This was a prospective, observational study conducted at a single clinical U.S. site. Eligible participants aged 18 or older were enrolled and assigned to one of two study groups: 1) individuals with no corneal pathology, eyelid margin disease, or conditions qualifying for the other sub-group – "Normal" subgroup; 2) those with four specified corneal conditions (soft and hard contact lens wearers, post-refractive surgery, dry eye, keratoconus) – "Cornea" subgroup. Three acceptable quality scans were acquired from each study eye using each scan pattern - Solix Corneal Map scan and Avanti Pachymetry Wide, with each of three Solix/Avanti instrument/operator pairs. Post-acquisition image review of signal strength, pupil alignment, eyelid artifact, scan range, and motion artifact were conducted on all scans. 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 subgroup using a random-effects analysis of variance (ANOVA) model. Reproducibility is the sum of Residual, DevOp, and Subject:DevOp variance components. Repeatability and reproducibility limits are $2.8 \times SD$ (standard deviation). Agreement between SOLIX and Avanti was evaluated with the estimation of the 95% limits of agreement (LOAs), Bland-Altman plots, and Deming regression analyses stratified by sub-group.

Results

63 participants were enrolled and 61 were eligible (30 "Normal," 31 in "Cornea" subgroup [7 with dry eye, 7 with contact lens wear, 8 post-refractive surgery and 9 with keratoconus]). The mean age in the "Normal" sub-group was 43 ± 16.9 (range 22-67) and 43 ± 15.3 (range 22-74) in the "cornea" sub-group. 52% of the cohort are women and 48% are men. 69% of the cohort was Caucasian and 31% were Native American.

556 Solix scans and 555 Avanti XR scans were acquired across 6 devices. Scan attrition for poor image quality was similar for both devices (<3%). The manual edit rate was 10.0% and 14.8% for SOLIX and XR, respectively, with majority of edits performed for KCN eyes (63.6% for SOLIX, 50.6% for Avanti XR).

The repeatability and reproducibility (R&R) results are show in the tables below.

Parameter (φ9 mm)	Unit	Epithelia (Epi)					Cornea (Pachy)					Stroma				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
C(2)	µm	53.6	0.7	0.9	1.6%	2.4	527.1	1.3	1.9	0.4%	5.3	473.4	1.0	1.8	0.4%	5.0
T(2-5)	µm	52.8	0.8	0.9	1.6%	2.4	537.1	2.4	3.1	0.6%	8.6	484.2	2.4	3.0	0.6%	8.3
ST(2-5)	µm	52.7	0.8	1.0	2.0%	2.9	552.9	4.3	5.8	1.0%	16.2	500.2	4.2	5.6	1.1%	15.6
S(2-5)	µm	53.0	0.9	1.2	2.2%	3.2	565.7	5.4	7.5	1.3%	21.0	512.7	5.4	7.4	1.4%	20.6
SN(2-5)	µm	53.9	0.9	1.1	2.0%	3.1	563.5	4.9	6.6	1.2%	18.6	509.5	4.7	6.4	1.3%	17.9
N(2-5)	µm	54.1	0.7	0.9	1.7%	2.5	553.5	3.8	4.9	0.9%	13.8	499.4	3.7	4.8	1.0%	13.3
IN(2-5)	µm	54.7	0.7	0.8	1.5%	2.3	546.6	3.7	4.5	0.8%	12.7	491.9	3.6	4.4	0.9%	12.3
I(2-5)	µm	54.9	0.8	0.9	1.6%	2.5	541.0	3.6	4.6	0.9%	12.9	486.0	3.5	4.5	0.9%	12.5
IT(2-5)	µm	54.0	0.8	0.9	1.7%	2.5	534.6	2.8	3.4	0.6%	9.5	480.6	2.7	3.3	0.7%	9.3
T(5-7)	µm	53.3	0.6	0.8	1.5%	2.2	569.0	3.8	5.1	0.9%	14.3	515.7	3.8	4.9	0.9%	13.7
ST(5-7)	µm	52.0	0.7	1.0	1.9%	2.8	597.3	6.0	8.1	1.4%	22.8	545.3	6.2	8.1	1.5%	22.7
S(5-7)	µm	51.7	1.0	1.3	2.5%	3.6	618.0	6.7	10.2	1.7%	28.7	566.3	6.9	10.5	1.8%	29.3
SN(5-7)	µm	54.8	1.0	1.2	2.2%	3.4	614.7	6.4	8.5	1.4%	23.8	559.8	6.4	8.4	1.5%	23.5
N(5-7)	µm	54.8	0.8	1.0	1.8%	2.7	596.4	5.5	7.2	1.2%	20.0	541.6	5.2	6.8	1.3%	19.1
IN(5-7)	µm	54.9	0.7	0.8	1.4%	2.2	587.7	5.6	7.0	1.2%	19.7	532.8	5.5	7.0	1.3%	19.6
I(5-7)	µm	55.1	0.6	0.8	1.4%	2.1	580.5	5.7	7.1	1.2%	19.9	525.4	5.7	7.2	1.4%	20.1
IT(5-7)	µm	54.8	0.6	0.7	1.3%	2.0	567.7	4.8	5.9	1.0%	16.4	512.9	4.7	5.8	1.1%	16.1
T(7-9)	µm	53.3	0.9	1.2	2.2%	3.3	610.0	7.0	8.9	1.5%	24.8	556.7	7.2	8.8	1.6%	24.6
ST(7-9)	µm	49.6	1.1	1.2	2.5%	3.5	648.9	8.7	11.4	1.8%	32.0	599.2	9.1	11.9	2.0%	33.2
S(7-9)	µm	48.2	1.2	1.5	3.1%	4.2	668.8	8.8	13.8	2.1%	38.7	620.6	9.1	14.1	2.3%	39.6
SN(7-9)	µm	53.1	1.2	1.8	3.3%	5.0	663.4	7.1	9.7	1.5%	27.3	610.2	7.4	10.0	1.6%	28.0
N(7-9)	µm	56.8	0.8	0.9	1.6%	2.6	644.9	6.9	9.1	1.4%	25.4	588.1	6.6	8.6	1.5%	24.1
IN(7-9)	µm	54.9	0.8	1.0	1.7%	2.6	637.1	7.9	9.9	1.6%	27.7	582.2	7.9	9.9	1.7%	27.7
I(7-9)	µm	54.0	0.8	1.2	2.1%	3.2	628.3	8.1	10.2	1.6%	28.6	574.2	8.3	10.6	1.8%	29.7
IT(7-9)	µm	55.1	0.9	1.1	1.9%	3.0	609.9	7.5	8.7	1.4%	24.4	554.8	7.6	8.7	1.6%	24.5

Cornea (N=279scans)																
		Epithelia (Epi)					Cornea (Pachy)					Stroma				
Parameter (φ9 mm)	Unit	Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
C(2)	µm	54.3	0.8	1.0	1.8%	2.8	508.5	2.3	3.1	0.6%	8.6	454.1	2.1	3.0	0.7%	8.5
T(2-5)	µm	53.6	1.1	1.4	2.5%	3.8	524.5	4.5	6.5	1.2%	18.2	470.9	4.7	6.7	1.4%	18.9
ST(2-5)	µm	53.4	1.3	1.6	3.0%	4.5	543.1	5.0	7.1	1.3%	19.9	489.7	4.9	6.9	1.4%	19.3
S(2-5)	µm	53.9	1.1	1.3	2.4%	3.6	556.5	5.5	7.3	1.3%	20.4	502.6	5.6	7.5	1.5%	20.9
SN(2-5)	µm	55.0	0.9	1.1	2.1%	3.2	553.8	5.4	6.4	1.2%	18.0	498.7	5.4	6.6	1.3%	18.4
N(2-5)	µm	56.0	0.9	1.1	1.9%	3.0	542.2	4.7	5.6	1.0%	15.7	486.2	4.6	5.5	1.1%	15.5
IN(2-5)	µm	55.9	1.0	1.3	2.3%	3.6	531.1	4.5	6.2	1.2%	17.4	475.1	4.5	5.9	1.2%	16.6
I(2-5)	µm	55.0	1.2	1.5	2.8%	4.3	518.9	4.5	6.6	1.3%	18.6	463.8	4.7	7.0	1.5%	19.7
IT(2-5)	µm	54.6	1.2	1.5	2.7%	4.2	513.8	3.6	4.2	0.8%	11.8	459.2	3.9	4.3	0.9%	12.1
T(5-7)	µm	52.5	1.0	1.6	3.1%	4.6	563.0	5.5	7.4	1.3%	20.8	510.5	5.6	7.0	1.4%	19.7
ST(5-7)	µm	51.5	1.2	1.5	2.8%	4.1	592.3	6.5	8.9	1.5%	24.9	540.8	6.8	9.2	1.7%	25.9
S(5-7)	µm	51.2	1.4	1.8	3.5%	5.0	614.2	6.9	9.2	1.5%	25.8	563.0	7.0	9.5	1.7%	26.6
SN(5-7)	µm	53.2	1.0	1.4	2.6%	3.9	608.6	6.4	8.2	1.3%	23.0	555.4	6.5	8.4	1.5%	23.6
N(5-7)	µm	54.7	0.9	1.2	2.1%	3.2	588.2	6.0	7.4	1.3%	20.7	533.4	6.0	7.4	1.4%	20.7
IN(5-7)	µm	54.6	1.0	1.2	2.1%	3.2	575.2	6.0	8.0	1.4%	22.4	520.5	6.1	8.1	1.6%	22.6
I(5-7)	µm	53.7	1.1	1.2	2.3%	3.4	563.1	6.0	8.1	1.4%	22.6	509.3	6.3	8.1	1.6%	22.6
IT(5-7)	µm	53.4	1.0	1.2	2.2%	3.3	554.7	5.5	6.3	1.1%	17.5	501.3	5.6	6.2	1.2%	17.3
T(7-9)	µm	52.3	1.2	1.4	2.7%	4.0	607.9	7.3	9.3	1.5%	25.9	555.6	7.3	9.3	1.7%	25.9
ST(7-9)	µm	49.5	1.3	1.7	3.3%	4.6	644.7	8.9	12.2	1.9%	34.2	595.2	8.9	12.3	2.1%	34.4
S(7-9)	µm	49.5	1.6	2.2	4.4%	6.2	669.9	9.4	13.2	2.0%	37.0	620.4	9.6	13.3	2.1%	37.1
SN(7-9)	µm	52.1	1.3	1.6	3.0%	4.4	658.3	6.5	8.9	1.4%	25.0	606.2	6.8	9.2	1.5%	25.9
N(7-9)	µm	55.6	1.0	1.2	2.1%	3.3	635.2	6.7	8.2	1.3%	23.0	579.6	6.5	7.8	1.3%	21.8
IN(7-9)	µm	54.2	0.9	1.0	1.9%	2.9	624.5	7.4	9.9	1.6%	27.7	570.3	7.4	9.6	1.7%	26.9
I(7-9)	µm	52.9	0.8	1.0	2.0%	2.9	612.4	8.2	10.6	1.7%	29.6	559.5	8.4	10.8	1.9%	30.3
IT(7-9)	µm	54.0	0.9	1.1	2.1%	3.2	600.3	7.4	9.2	1.5%	25.7	546.3	7.1	9.0	1.6%	25.1

Solix OCT and OCTA Performance – Posterior Segment

This was a prospective, observational study conducted at a single clinical U.S. site. Eligible participants aged 18 or older were enrolled and assigned to one of three study groups: 1) individuals with no ocular disease ("normal"); 2) individuals with glaucoma of varying severity (with confirmed glaucomatous visual field defect and/or glaucomatous optic nerve changes), and 3) individuals with pathological retinal conditions. One eligible eye per participant was designated the study eye. Three SOLIX and three Avanti devices were paired with designated device operators to form six different device-operator pairs ("configurations"). Three acceptable quality scans were acquired from each study eye using each scan pattern with each of the three Solix/Avanti configurations. All scans underwent post-acquisition image quality review. 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 subgroup using a random-effects analysis of variance (ANOVA) model. Agreement between SOLIX and Avanti was evaluated with the estimation of the 95% limits of agreement (LOAs), Bland-Altman plots, and Deming regression analyses stratified by sub-group.

Results
93 participants were enrolled and 83 participants completed the study (30 "normal," 25 "Glaucoma", 28 "Retina" subgroup). 44 (53%) participants are women and 39 (47%) are men. The mean age was 65.5±15.3 (range 21 to 91). 86 (94.5%) participants were Caucasian. The glaucoma sub-group consisted of 10, 7, and 8 participants with early, moderate, and advanced

glaucoma, respectively. Mean visual field mean deviation (MD) was -2.00, -4.40, and -9.89 dB in early, moderate, and severe glaucoma participants, respectively, and ranged from -13.84 dB to -0.72 dB. Mean pattern standard deviation (PSD) was -2.27, -3.83, and -9.30 dB in early, moderate, and severe glaucoma participants, respectively, and ranged from -1.76 dB to -13.65 dB. Glaucomatous optic nerve findings were observed in all glaucoma sub-group participants. The retinal conditions represented in the "Retina" sub-group were exudative and non-exudative age-related macular degeneration ("wet" and "dry" AMD; n=10 and 6, respectively), proliferative and non-proliferative diabetic retinopathy (PDR and NPDR, n=6 and 2, respectively), and other retinal vascular conditions (adult vitelliform dystrophy [n=1] and retinitis pigmentosa [n=2]).

Scan acceptability rates ranged from 93.7% to 100%. The main reasons for scan disqualification were motion artifacts for Disc Cube scan and local weak signal for AngioVue Retina. Across the five study scan types and sub-groups, the manual editing rates for segmentation boundaries were 0.1% for ILM (Retina Cube scan), 5.2% for IPL (Retina Cube Scan), 0.1% for RPE (Retina Cube scan), and 3.9% for NFL (AngioVue Disc scan); the foveal center detection correction rates were 0.5% for Wellness scan, 0.7% for AngioVue Retina scan and 0.7% for Retina Cube scan; the FAZ boundary manual editing rate was 19.7% for AngioVue Retina scans; the disc margin manual editing was performed for the baseline scan in 1.5% of study eyes per instrument.

Structural Parameters of the Macula Scans – R&R Results

		AngioVue Retina (N = 269)					Retina Cube (N=269)					Wellness (N=270)				
			Repeatability	Reproducibility				Repeatability	Reproducibility				Repeatability	Reproducibility		
Measurement	Unit	Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*
GCC		ETDRS Grid (Ø 6mm)														
C(1)_GCC	µm	60.7 (9.6)	0.7	1.0	1.6%	2.7	61.3 (9.4)	1.1	1.4	2.2%	3.8	67.9 (9.1)	1.3	1.4	2.0%	3.8
T(1-3)_GCC	µm	102.2 (6.6)	0.7	0.9	0.9%	2.6	103.1 (6.5)	0.7	1.0	0.9%	2.7	102.0 (6.4)	0.7	1.0	1.0%	2.7
S(1-3)_GCC	µm	114.5 (7.4)	0.7	1.1	0.9%	3.0	114.2 (7.3)	0.9	1.2	1.1%	3.4	111.6 (7.9)	1.0	1.2	1.1%	3.5
N(1-3)_GCC	µm	112.6 (6.9)	0.8	1.0	0.9%	2.8	112.9 (6.8)	1.0	1.2	1.1%	3.3	112.3 (6.6)	0.9	1.2	1.1%	3.4
I(1-3)_GCC	µm	114.9 (7.0)	0.7	1.1	1.0%	3.1	114.3 (7.0)	0.9	1.2	1.0%	3.3	111.1 (7.3)	0.9	1.3	1.1%	3.5
S-Hemi (1-3)_GCC	µm	110.7 (6.9)	0.6	0.9	0.8%	2.6	110.9 (6.8)	0.7	1.0	0.9%	2.9	109.6 (7.1)	0.8	1.0	0.9%	2.9
I-Hemi (1-3)_GCC	µm	111.4 (6.7)	0.6	0.9	0.8%	2.6	111.4 (6.6)	0.7	1.0	0.9%	2.8	109.6 (6.6)	0.8	1.1	1.0%	3.0
All(1-3)_GCC	µm	111.1 (6.7)	0.5	0.9	0.8%	2.4	111.1 (6.6)	0.6	0.9	0.8%	2.6	109.6 (6.8)	0.7	1.0	0.9%	2.7
T(3-6)_GCC	µm	84.2 (7.2)	0.8	1.1	1.3%	3.0	84.7 (7.1)	0.8	1.0	1.2%	2.7	80.1 (6.6)	0.8	1.0	1.3%	2.8
S(3-6)_GCC	µm	100.7 (8.2)	0.8	1.0	1.0%	2.8	99.3 (8.2)	0.9	1.1	1.1%	3.0	91.2 (7.8)	1.0	1.3	1.5%	3.8
N(3-6)_GCC	µm	119.3 (8.8)	0.6	0.9	0.8%	2.6	118.6 (8.6)	0.8	1.1	0.9%	3.1	115.4 (9.5)	1.1	1.5	1.3%	4.3
I(3-6)_GCC	µm	100.2 (8.4)	0.7	1.1	1.1%	3.0	99.0 (8.3)	0.9	1.2	1.2%	3.4	95.4 (8.3)	1.3	2.0	2.1%	5.7
S-Hemi (3-6)_GCC	µm	100.7 (7.6)	0.6	0.9	0.9%	2.4	100.0 (7.5)	0.7	0.9	0.9%	2.5	93.4 (7.4)	0.9	1.2	1.2%	3.2
I-Hemi (3-6)_GCC	µm	101.5 (8.1)	0.6	0.9	0.9%	2.6	100.8 (8.0)	0.8	1.0	1.0%	2.9	96.8 (7.9)	1.0	1.6	1.7%	4.5
All (3-6)_GCC	µm	101.1 (7.6)	0.5	0.8	0.8%	2.3	100.4 (7.5)	0.6	0.9	0.9%	2.4	95.1 (7.3)	0.8	1.2	1.3%	3.5
S-Hemi (0-6)_GCC	µm	101.8 (7.0)	0.6	0.8	0.8%	2.3	101.3 (6.9)	0.6	0.8	0.8%	2.3	96.3 (6.8)	0.8	1.0	1.1%	2.8
I-Hemi (0-6)_GCC	µm	102.6 (7.2)	0.6	0.9	0.9%	2.5	102.0 (7.2)	0.7	0.9	0.9%	2.6	98.9 (7.2)	0.9	1.4	1.4%	3.8
All (0-6)_GCC	µm	102.2 (6.9)	0.5	0.8	0.8%	2.2	101.7 (6.8)	0.6	0.8	0.8%	2.2	97.6 (6.8)	0.7	1.1	1.1%	3.0
GCC		ETDRS Grid (Ø 6mm)										7mm x 8mm				
WI_GCC	µm	103.3 (7.0)	0.5	0.8	0.7%	2.2	102.7 (6.9)	0.6	0.8	0.8%	2.3	92.1 (6.2)	0.7	1.1	1.2%	3.2
WI-S-Hemi_GCC	µm	102.2 (7.1)	0.6	0.8	0.8%	2.3	101.6 (7.0)	0.7	0.9	0.9%	2.4	91.1 (6.4)	0.8	1.0	1.1%	2.9
WI-I-Hemi_GCC	µm	104.4 (7.4)	0.6	0.9	0.8%	2.5	103.7 (7.4)	0.7	1.0	1.0%	2.8	93.0 (6.7)	0.9	1.5	1.6%	4.2
FLV_GCC	%	0.57 (0.92)	0.1	0.2	29.5%	0.5	0.54 (0.91)	0.2	0.2	32.2%	0.5	NA				
GLV_GCC	%	3.6 (3.7)	0.3	0.5	12.3%	1.3	3.6 (3.7)	0.3	0.5	13.8%	1.4					
Retina Thickness		ETDRS Grid (Ø 6mm)														
C(1)_R	µm	269.6 (21.0)	1.0	1.6	0.6%	4.4	270.4 (21.0)	1.6	2.3	0.9%	6.5	269.1 (21.0)	1.4	2.1	0.8%	5.9
T(1-3)_R	µm	312.3 (13.9)	1.0	1.5	0.5%	4.2	313.5 (14.1)	1.3	1.9	0.6%	5.3	311.7 (14.1)	1.0	1.6	0.5%	4.5
S(1-3)_R	µm	327.2 (14.6)	1.0	1.8	0.5%	5.0	328.0 (14.6)	1.4	2.3	0.7%	6.3	325.6 (14.5)	1.2	1.9	0.6%	5.3
N(1-3)_R	µm	329.9 (13.9)	1.0	1.6	0.5%	4.5	330.9 (14.1)	1.4	2.1	0.6%	5.8	328.0 (14.3)	1.2	1.8	0.5%	4.9
I(1-3)_R	µm	322.2 (13.6)	1.0	1.6	0.5%	4.5	323.2 (14.0)	1.6	2.0	0.6%	5.5	322.3 (13.9)	1.1	1.6	0.5%	4.4
S-Hemi(1-3)_R	µm	324.3 (14.2)	0.9	1.6	0.5%	4.5	325.2 (14.2)	1.2	2.0	0.6%	5.7	322.6 (14.2)	1.1	1.7	0.5%	4.9
I-Hemi-(1-3)_R	µm	321.4 (13.3)	0.9	1.5	0.5%	4.1	322.6 (13.7)	1.4	1.8	0.6%	5.1	321.1 (13.7)	1.0	1.5	0.5%	4.1
All(1-3)_R	µm	322.9 (13.7)	0.8	1.5	0.4%	4.1	323.9 (13.8)	1.1	1.8	0.6%	5.1	321.9 (13.8)	0.9	1.5	0.5%	4.3
T(3-6)_R	µm	262.7 (14.5)	1.1	1.4	0.5%	4.0	264.8 (14.5)	1.4	1.8	0.7%	5.1	274.0 (15.4)	1.0	1.6	0.6%	4.4
S(3-6)_R	µm	282.5 (14.6)	1.0	1.7	0.6%	4.7	283.5 (14.5)	1.5	2.0	0.7%	5.6	290.4 (15.1)	1.2	1.7	0.6%	4.8
N(3-6)_R	µm	300.9 (15.5)	0.9	1.4	0.5%	3.9	302.3 (15.6)	1.1	1.7	0.6%	4.8	302.7 (16.2)	1.1	1.6	0.5%	4.6
I(3-6)_R	µm	269.7 (13.5)	1.0	1.4	0.5%	4.0	270.7 (13.8)	1.4	1.7	0.6%	4.8	278.9 (15.1)	1.3	1.8	0.6%	5.0
S-Hemi(3-6)_R	µm	282.7 (14.6)	0.8	1.4	0.5%	4.0	284.0 (14.5)	1.2	1.7	0.6%	4.8	289.6 (15.1)	1.0	1.5	0.5%	4.2
I-Hemi(3-6)_R	µm	275.2 (13.8)	0.9	1.3	0.5%	3.7	276.7 (14.0)	1.2	1.6	0.6%	4.5	283.3 (15.0)	1.0	1.5	0.5%	4.3
All(3-6)_R	µm	279.0 (14.0)	0.8	1.3	0.5%	3.5	280.3 (14.0)	1.0	1.5	0.5%	4.3	286.5 (14.9)	0.9	1.4	0.5%	3.9
S-Hemi(0-6)_R	µm	291.6 (13.9)	0.8	1.4	0.5%	3.9	292.8 (13.9)	1.1	1.7	0.6%	4.8	296.4 (14.4)	1.0	1.5	0.5%	4.2
I-Hemi(0-6)_R	µm	285.3 (13.2)	0.9	1.3	0.4%	3.6	286.7 (13.4)	1.2	1.6	0.6%	4.5	291.4 (14.1)	0.9	1.5	0.5%	4.1
All(0-6)_R	µm	288.5 (13.4)	0.7	1.3	0.4%	3.5	289.8 (13.5)	1.0	1.6	0.5%	4.4	293.9 (14.1)	0.8	1.4	0.5%	3.9
All (0-6)_R_Vol	mm³	8.2 (0.38)	0.02	0.04	0.5%	0.10	8.2 (0.38)	0.03	0.05	0.6%	0.13	NA				

Measurement	Unit	AngioVue Retina (N = 224)					Retina Cube (N=225)					Wellness (N=225)				
		Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*	Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*	Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*
GCC		**ETDRS Grid (Ø 6mm)**														
C(1)_GCC	µm	51.9 (10.7)	0.8	1.0	2.0%	2.9	52.1 (11.0)	1.3	1.6	3.0%	4.4	58.1 (11.0)	1.3	1.6	2.7%	4.4
T(1-3)_GCC	µm	82.6 (11.6)	0.7	0.8	1.0%	2.4	83.2 (11.6)	0.9	1.0	1.2%	2.8	82.2 (11.0)	1.0	1.1	1.3%	3.1
S(1-3)_GCC	µm	95.6 (13.0)	0.9	1.0	1.0%	2.7	94.6 (12.6)	0.9	1.0	1.1%	2.9	91.6 (12.0)	1.0	1.3	1.4%	3.5
N(1-3)_GCC	µm	96.1 (12.1)	0.8	1.0	1.0%	2.7	96.3 (11.8)	1.0	1.0	1.0%	2.8	95.4 (11.7)	0.9	1.0	1.1%	2.9
I(1-3)_GCC	µm	92.1 (13.2)	0.7	0.9	0.9%	2.4	91.1 (12.7)	0.9	1.0	1.1%	2.9	87.1 (11.8)	0.9	1.1	1.2%	3.0
S-Hemi (1-3)_GCC	µm	92.7 (12.2)	0.7	0.8	0.9%	2.3	92.5 (11.9)	0.8	0.9	1.0%	2.5	90.8 (11.4)	0.8	1.0	1.1%	2.8
I-Hemi (1-3)_GCC	µm	90.4 (12.4)	0.6	0.8	0.9%	2.3	90.1 (12.1)	0.7	0.9	1.0%	2.4	87.5 (11.3)	0.8	0.9	1.1%	2.6
All(1-3)_GCC	µm	91.6 (11.5)	0.5	0.7	0.7%	1.9	91.3 (11.3)	0.6	0.7	0.8%	2.0	89.1 (10.5)	0.6	0.8	0.9%	2.3
T(3-6)_GCC	µm	69.4 (8.4)	0.7	0.9	1.3%	2.5	69.5 (8.3)	0.8	1.0	1.4%	2.8	66.1 (7.8)	0.8	0.9	1.4%	2.5
S(3-6)_GCC	µm	81.5 (12.7)	0.7	0.8	1.0%	2.2	80.0 (12.3)	0.9	1.1	1.4%	3.1	72.2 (12.3)	1.1	1.4	1.9%	3.8
N(3-6)_GCC	µm	97.4 (11.8)	0.6	0.8	0.8%	2.1	96.2 (11.5)	1.0	1.3	1.4%	3.7	90.9 (12.0)	1.0	1.4	1.6%	4.0
I(3-6)_GCC	µm	76.5 (12.1)	0.7	0.8	1.0%	2.2	75.2 (11.5)	0.8	1.1	1.5%	3.2	70.6 (12.1)	1.1	1.5	2.1%	4.1
S-Hemi (3-6)_GCC	µm	83.2 (11.1)	0.6	0.7	0.8%	1.8	82.2 (10.8)	0.7	0.9	1.1%	2.6	75.4 (10.9)	0.8	1.1	1.5%	3.1
I-Hemi (3-6)_GCC	µm	79.2 (11.0)	0.6	0.7	0.9%	1.9	78.3 (10.6)	0.7	1.0	1.2%	2.7	73.2 (11.0)	0.9	1.1	1.5%	3.2
All (3-6)_GCC	µm	81.2 (9.7)	0.5	0.6	0.7%	1.5	80.2 (9.4)	0.6	0.8	1.0%	2.2	74.3 (9.7)	0.7	0.9	1.2%	2.6
S-Hemi (0-6)_GCC	µm	84.5 (10.9)	0.5	0.6	0.7%	1.7	83.6 (10.6)	0.6	0.8	0.9%	2.2	78.3 (10.6)	0.7	1.0	1.3%	2.8
I-Hemi (0-6)_GCC	µm	81.0 (10.7)	0.5	0.6	0.8%	1.8	80.2 (10.3)	0.6	0.8	1.0%	2.3	76.0 (10.4)	0.8	1.0	1.3%	2.7
All (0-6)_GCC	µm	82.7 (9.7)	0.4	0.5	0.7%	1.5	81.9 (9.4)	0.6	0.7	0.9%	2.0	77.1 (9.4)	0.6	0.8	1.0%	2.3
GCC		**ETDRS Grid (Ø 6mm)**										**7mm x 8mm**				
WI_GCC	µm	82.5 (10.3)	0.4	0.5	0.6%	1.4	81.7 (9.9)	0.6	0.7	0.9%	2.1	73.4 (8.9)	0.7	0.8	1.1%	2.3
WI-S-Hemi_GCC	µm	84.1 (11.6)	0.5	0.6	0.8%	1.8	83.2 (11.3)	0.7	0.9	1.0%	2.4	74.6 (10.2)	0.8	1.0	1.3%	2.8
WI-I-Hemi_GCC	µm	80.9 (11.5)	0.5	0.7	0.8%	1.8	80.1 (11.1)	0.7	0.9	1.1%	2.5	72.1 (9.7)	0.9	1.0	1.4%	2.9
FLV_GCC	%	5.7 (3.5)	0.4	0.4	6.9%	1.1	5.5 (3.3)	0.4	0.5	8.6%	1.3	NA				
GLV_GCC	%	19.8 (9.4)	0.4	0.5	2.5%	1.4	20.1 (9.1)	0.5	0.7	3.4%	1.9					
Retina Thickness		**ETDRS Grid (Ø 6mm)**														
C(1)_R	µm	252.2 (18.9)	1.0	1.7	0.7%	4.8	253.4 (19.3)	1.7	2.4	0.9%	6.7	252.1 (18.7)	1.6	2.1	0.8%	6.0
T(1-3)_R	µm	287.3 (17.4)	1.1	1.5	0.5%	4.3	288.9 (17.8)	1.4	2.0	0.7%	5.7	286.6 (17.6)	1.3	1.8	0.6%	5.0
S(1-3)_R	µm	300.7 (18.1)	1.1	1.6	0.5%	4.4	302.2 (18.3)	1.7	2.2	0.7%	6.1	299.5 (18.1)	1.4	1.9	0.6%	5.4
N(1-3)_R	µm	307.6 (16.9)	1.1	1.7	0.5%	4.7	309.6 (17.3)	1.4	1.9	0.6%	5.3	306.4 (17.2)	1.2	1.8	0.6%	4.9
I(1-3)_R	µm	293.6 (16.7)	1.3	1.8	0.6%	5.2	295.2 (17.1)	1.5	2.0	0.7%	5.6	293.9 (17.1)	1.2	1.7	0.6%	4.7
S-Hemi(1-3)_R	µm	299.6 (17.4)	1.0	1.5	0.5%	4.2	301.2 (17.8)	1.5	1.9	0.6%	5.4	298.4 (17.4)	1.2	1.8	0.6%	5.0
I-Hemi-(1-3)_R	µm	294.9 (16.6)	1.0	1.6	0.5%	4.5	296.7 (17.0)	1.2	1.9	0.6%	5.2	294.8 (17.0)	1.0	1.6	0.5%	4.4
All(1-3)_R	µm	297.3 (16.5)	0.9	1.4	0.5%	4.0	299.0 (16.9)	1.1	1.7	0.6%	4.8	296.6 (16.8)	1.0	1.6	0.5%	4.4
T(3-6)_R	µm	241.9 (17.1)	1.1	1.5	0.6%	4.2	244.2 (17.7)	1.4	1.9	0.8%	5.2	250.9 (18.3)	1.3	1.7	0.7%	4.9
S(3-6)_R	µm	255.5 (20.0)	1.0	1.5	0.6%	4.3	257.3 (20.6)	1.7	2.2	0.8%	6.1	262.9 (20.5)	1.5	1.9	0.7%	5.4
N(3-6)_R	µm	273.3 (16.6)	1.0	1.4	0.5%	4.0	275.4 (16.9)	1.2	1.7	0.6%	4.9	276.6 (17.5)	1.2	1.6	0.6%	4.3
I(3-6)_R	µm	239.8 (16.5)	1.1	1.5	0.6%	4.3	241.3 (17.1)	1.5	1.8	0.7%	5.0	248.5 (17.9)	1.2	1.6	0.6%	4.5
S-Hemi(3-6)_R	µm	258.2 (18.1)	0.8	1.3	0.5%	3.7	260.2 (18.7)	1.3	1.8	0.7%	5.1	264.5 (18.8)	1.2	1.7	0.7%	4.8
I-Hemi(3-6)_R	µm	247.1 (16.2)	1.0	1.4	0.5%	3.9	248.9 (16.9)	1.3	1.7	0.6%	4.8	255.0 (17.2)	1.0	1.4	0.6%	4.0
All(3-6)_R	µm	252.7 (16.5)	0.7	1.2	0.5%	3.4	254.5 (17.0)	1.0	1.5	0.6%	4.3	259.7 (17.5)	0.9	1.4	0.5%	3.9
S-Hemi(0-6)_R	µm	267.3 (17.3)	0.8	1.3	0.5%	3.7	269.1 (17.7)	1.3	1.8	0.7%	4.9	271.7 (17.8)	1.2	1.7	0.6%	4.7
I-Hemi(0-6)_R	µm	257.8 (15.6)	0.9	1.4	0.5%	3.8	259.7 (16.2)	1.2	1.7	0.6%	4.7	263.8 (16.7)	1.0	1.4	0.5%	3.9
All(0-6)_R	µm	262.6 (15.9)	0.7	1.2	0.5%	3.4	264.4 (16.4)	1.0	1.5	0.6%	4.3	267.7 (16.6)	0.9	1.4	0.5%	3.9
All (0-6)_R_Vol	mm³	7.4 (0.45)	0.02	0.04	0.5%	0.10	7.5 (0.46)	0.03	0.05	0.6%	0.13	NA				

Measurement	Unit	AngioVue Retina (N = 252)					Retina Cube (N=251)					Wellness (N=250)				
			Repeatability	Reproducibility				Repeatability	Reproducibility				Repeatability	Reproducibility		
		Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*
GCC		**ETDRS Grid (Ø 6mm)**														
C(1)_GCC	µm	55.4 (11.5)	0.9	1.0	1.8%	2.8	55.3 (11.6)	1.3	1.6	2.9%	4.4	59.8 (12.7)	2.4	3.2	5.3%	8.8
T(1-3)_GCC	µm	95.2 (11.2)	1.0	1.1	1.2%	3.1	95.3 (11.5)	0.9	1.0	1.1%	2.8	92.9 (12.5)	1.4	2.3	2.5%	6.5
S(1-3)_GCC	µm	107.7 (13.1)	0.9	1.0	0.9%	2.7	106.6 (12.7)	1.1	1.2	1.1%	3.3	102.9 (15.4)	1.5	5.0	4.9%	14.0
N(1-3)_GCC	µm	106.8 (13.7)	0.9	1.0	1.0%	2.9	106.8 (13.8)	1.1	1.2	1.1%	3.2	104.8 (15.1)	2.6	4.3	4.1%	12.2
I(1-3)_GCC	µm	107.7 (12.3)	0.8	1.0	0.9%	2.8	106.5 (12.6)	1.1	1.2	1.1%	3.4	103.2 (13.3)	1.7	1.8	1.7%	5.0
S-Hemi (1-3)_GCC	µm	103.7 (12.4)	0.9	0.9	0.9%	2.5	103.3 (12.2)	0.9	0.9	0.9%	2.5	100.8 (14.4)	1.3	4.5	4.5%	12.6
I-Hemi (1-3)_GCC	µm	104.9 (12.0)	0.7	0.9	0.8%	2.4	104.3 (12.2)	0.9	1.0	0.9%	2.7	101.9 (12.9)	1.6	1.8	1.7%	5.0
All (1-3)_GCC	µm	104.3 (12.1)	0.7	0.7	0.7%	2.1	103.8 (12.1)	0.7	0.7	0.7%	2.0	101.3 (13.3)	1.3	2.8	2.8%	8.0
T(3-6)_GCC	µm	84.6 (11.4)	0.6	0.8	0.9%	2.2	84.5 (11.4)	0.7	0.9	1.0%	2.4	78.9 (10.6)	1.0	1.3	1.7%	3.7
S(3-6)_GCC	µm	99.2 (12.1)	0.7	1.1	1.1%	3.1	97.6 (12.1)	1.1	1.2	1.2%	3.3	88.0 (13.7)	1.3	2.6	2.9%	7.2
N(3-6)_GCC	µm	114.9 (12.9)	0.5	0.7	0.6%	1.9	113.7 (13.1)	0.9	1.1	0.9%	3.0	108.3 (13.1)	1.5	2.9	2.7%	8.1
I(3-6)_GCC	µm	98.7 (12.3)	0.7	1.0	1.0%	2.8	96.9 (12.4)	1.2	1.6	1.7%	4.5	91.3 (11.9)	1.7	2.3	2.5%	6.5
S-Hemi (3-6)_GCC	µm	98.9 (11.0)	0.5	0.8	0.8%	2.2	97.8 (11.1)	0.8	0.9	0.9%	2.6	89.7 (12.2)	1.0	2.3	2.6%	6.5
I-Hemi (3-6)_GCC	µm	99.9 (11.7)	0.5	0.8	0.8%	2.2	98.5 (11.7)	1.0	1.2	1.2%	3.4	92.8 (11.5)	1.3	1.8	2.0%	5.1
All (3-6)_GCC	µm	99.4 (11.1)	0.4	0.6	0.6%	1.6	98.2 (11.1)	0.7	0.9	0.9%	2.5	91.3 (11.4)	0.9	1.7	1.9%	4.9
S-Hemi (0-6)_GCC	µm	98.8 (10.4)	0.5	0.7	0.7%	2.0	97.8 (10.4)	0.7	0.8	0.8%	2.2	91.3 (11.7)	0.8	2.6	2.9%	7.4
I-Hemi (0-6)_GCC	µm	99.7 (11.1)	0.5	0.7	0.7%	2.0	98.6 (11.1)	0.8	1.0	1.0%	2.8	93.9 (11.1)	1.2	1.6	1.7%	4.5
All (0-6)_GCC	µm	99.3 (10.5)	0.4	0.6	0.6%	1.5	98.2 (10.6)	0.6	0.8	0.8%	2.1	92.6 (11.1)	0.8	1.8	2.0%	5.2
GCC		**ETDRS Grid (Ø 6mm)**										**7mm x 8mm**				
WI_GCC	µm	100.8 (10.7)	0.4	0.7	0.6%	1.8	99.6 (10.7)	0.7	0.9	0.9%	2.5	88.7 (10.8)	0.7	1.6	1.8%	4.4
WI-S-Hemi_GCC	µm	99.7 (10.9)	0.5	0.8	0.8%	2.2	98.6 (10.9)	0.8	0.9	0.9%	2.6	87.6 (10.8)	0.9	2.1	2.4%	6.0
WI-I-Hemi_GCC	µm	101.9 (11.1)	0.6	0.9	0.9%	2.6	100.5 (11.1)	1.0	1.3	1.3%	3.5	89.7 (10.1)	1.1	1.7	1.9%	4.7
FLV_GCC	%	1.7 (2.2)	0.3	0.3	15.8%	0.8	1.8 (2.3)	0.3	0.3	18.3%	0.9	NA				
GLV_GCC	%	6.4 (6.3)	0.3	0.5	7.9%	1.4	6.7 (6.6)	0.4	0.6	8.7%	1.6					
Retina Thickness		**ETDRS Grid (Ø 6mm)**														
C(1)_R	µm	232.1 (40.0)	1.2	1.7	0.7%	4.7	233.1 (40.0)	2.0	2.3	1.0%	6.6	231.4 (39.8)	1.9	2.9	1.3%	8.1
T(1-3)_R	µm	283.1 (35.8)	1.2	1.6	0.6%	4.5	284.2 (36.2)	1.4	1.8	0.6%	5.1	282.5 (34.9)	1.6	2.1	0.8%	5.9
S(1-3)_R	µm	292.3 (36.4)	1.3	1.6	0.6%	4.6	293.8 (36.8)	1.8	2.2	0.8%	6.2	291.4 (35.9)	1.6	2.3	0.8%	6.3
N(1-3)_R	µm	300.0 (36.6)	1.3	1.5	0.5%	4.3	301.6 (37.0)	1.5	1.9	0.6%	5.2	298.3 (36.0)	1.3	2.0	0.7%	5.5
I(1-3)_R	µm	292.7 (35.3)	1.1	1.3	0.5%	3.7	293.5 (35.7)	1.4	1.6	0.5%	4.4	291.8 (34.9)	1.6	2.6	0.9%	7.2
S-Hemi (1-3)_R	µm	291.0 (35.6)	0.9	1.3	0.4%	3.5	292.4 (36.0)	1.3	1.7	0.6%	4.9	289.9 (35.0)	1.4	2.0	0.7%	5.5
I-Hemi-(1-3)_R	µm	293.1 (35.3)	1.0	1.2	0.4%	3.4	294.1 (35.7)	1.2	1.5	0.5%	4.1	292.1 (34.7)	1.3	2.1	0.7%	5.8
All(1-3)_R	µm	292.0 (35.2)	0.8	1.1	0.4%	3.0	293.3 (35.6)	1.0	1.4	0.5%	3.9	291.0 (34.6)	1.1	1.8	0.6%	5.2
T(3-6)_R	µm	250.2 (30.4)	1.0	1.3	0.5%	3.7	251.5 (30.8)	1.2	1.7	0.7%	4.6	258.7 (31.9)	1.2	1.8	0.7%	5.1
S(3-6)_R	µm	261.8 (30.8)	0.9	1.2	0.5%	3.3	263.1 (31.2)	1.5	1.8	0.7%	5.0	267.3 (31.9)	1.5	2.1	0.8%	5.9
N(3-6)_R	µm	277.7 (30.2)	0.9	1.2	0.4%	3.5	278.8 (30.2)	1.2	1.5	0.5%	4.1	279.6 (30.5)	1.3	1.7	0.6%	4.8
I(3-6)_R	µm	254.2 (28.2)	0.9	1.4	0.6%	3.9	255.5 (25.6)	1.4	1.8	0.7%	5.0	261.0 (28.4)	1.5	1.9	0.7%	5.4
S-Hemi(3-6)_R	µm	262.8 (29.2)	0.7	1.0	0.4%	2.8	264.0 (29.6)	1.1	1.4	0.5%	4.1	268.1 (29.8)	1.3	1.8	0.7%	5.2
I-Hemi(3-6)_R	µm	259.2 (26.8)	0.8	1.2	0.5%	3.3	260.4 (27.1)	1.1	1.4	0.6%	4.0	265.3 (29.3)	1.2	1.6	0.6%	4.6
All(3-6)_R	µm	261.0 (27.7)	0.6	0.9	0.4%	2.6	262.2 (28.1)	0.9	1.2	0.5%	3.5	266.7 (29.2)	1.0	1.5	0.6%	4.3
S-Hemi(0-6)_R	µm	268.2 (29.4)	0.6	0.9	0.3%	2.6	269.5 (29.8)	1.0	1.4	0.5%	3.9	271.9 (29.9)	1.2	1.8	0.7%	5.0
I-Hemi(0-6)_R	µm	266.0 (27.7)	0.7	1.1	0.4%	3.1	267.2 (28.1)	1.0	1.3	0.5%	3.7	270.3 (29.6)	1.1	1.6	0.6%	4.6
All(0-6)_R	µm	267.1 (28.3)	0.6	0.9	0.3%	2.5	268.3 (28.7)	0.9	1.2	0.4%	3.4	271.1 (29.5)	1.0	1.6	0.6%	4.4
All (0-6)_R_Vol	mm³	7.5 (0.81)	0.02	0.04	0.5%	0.11	7.6 (0.83)	0.04	0.06	0.8%	0.16	NA				

Vascular Parameters of the Macula Scan – R&R Results

Normal Subjects

Superficial Vascular Complex (SVC)	Unit	N = 269					Deep Vascular Complex (DVC)	Unit	N = 269				
		Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*			Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*
SVC		**ETDRS Grid (Ø 6mm)**					**DVC**		**ETDRS Grid (Ø 6mm)**				
C(1)_SVC	%	29.7 (5.4)	2.1	2.6	8.7%	7.3	C(1)_DVC	%	33.0 (6.0)	2.2	2.8	8.6%	7.9
T(1-3)_SVC	%	47.5 (2.7)	1.9	2.5	5.3%	7.0	T(1-3)_DVC	%	53.6 (1.9)	1.7	2.0	3.7%	5.5
S(1-3)_SVC	%	48.3 (2.8)	2.1	2.6	5.4%	7.3	S(1-3)_DVC	%	53.3 (2.0)	1.8	2.0	3.7%	5.5
N(1-3)_SVC	%	47.2 (3.3)	2.3	2.8	6.0%	8.0	N(1-3)_DVC	%	53.3 (2.2)	1.9	2.2	4.0%	6.0
I(1-3)_SVC	%	48.3 (2.9)	2.0	2.7	5.5%	7.5	I(1-3)_DVC	%	53.4 (1.9)	1.7	1.8	3.5%	5.2
S-Hemi(1-3)_SVC	%	47.8 (2.6)	1.9	2.4	5.0%	6.8	S-Hemi(1-3)_DVC	%	53.5 (1.5)	1.2	1.6	2.9%	4.4
I-Hemi(1-3)_SVC	%	47.8 (2.7)	1.9	2.6	5.4%	7.2	I-Hemi(1-3)_DVC	%	53.4 (1.7)	1.4	1.7	3.2%	4.7
All(1-3)_SVC	%	47.8 (2.6)	1.8	2.4	5.1%	6.8	All(1-3)_DVC	%	53.4 (1.4)	1.1	1.4	2.6%	3.9
T(3-6)_SVC	%	44.0 (2.4)	1.5	2.2	4.9%	6.1	T(3-6)_DVC	%	53.2 (1.9)	1.7	1.9	3.7%	5.4
S(3-6)_SVC	%	47.5 (2.2)	1.4	1.7	3.7%	4.9	S(3-6)_DVC	%	52.5 (2.3)	1.9	2.3	4.4%	6.4
N(3-6)_SVC	%	50.9 (1.8)	1.3	1.5	3.0%	4.3	N(3-6)_DVC	%	52.4 (2.3)	1.9	2.3	4.3%	6.3
I(3-6)_SVC	%	47.4 (2.2)	1.3	1.7	3.7%	4.9	I(3-6)_DVC	%	52.3 (2.4)	1.9	2.4	4.6%	6.8
S-Hemi(3-6)_SVC	%	47.4 (2.0)	1.3	1.7	3.5%	4.7	S-Hemi(3-6)_DVC	%	52.7 (1.8)	1.4	1.8	3.4%	5.1
I-Hemi(3-6)_SVC	%	47.5 (1.9)	1.2	1.7	3.5%	4.7	I-Hemi(3-6)_DVC	%	52.5 (1.9)	1.3	1.9	3.6%	5.3
All(3-6)_SVC	%	47.5 (1.8)	1.2	1.6	3.4%	4.5	All(3-6)_DVC	%	52.6 (1.6)	1.1	1.6	3.1%	4.5
All(0-6)_SVC	%	47.1 (1.9)	1.3	1.7	3.7%	4.9	All(0-6)_DVC	%	52.3 (1.4)	1.0	1.4	2.7%	3.9
SVC		**6 mm x 6 mm**					**DVC**		**6 mm x 6 mm**				
WI_SVC	%	47.5 (1.8)	1.2	1.6	3.4%	4.5	WI_DVC	%	51.8 (1.7)	1.0	1.7	3.2%	4.7
WI-S-Hemi_SVC	%	47.5 (1.8)	1.3	1.6	3.4%	4.5	WI-S-Hemi_DVC	%	51.9 (1.8)	1.2	1.8	3.4%	4.9
WI-I-Hemi_SVC	%	47.5 (1.8)	1.2	1.7	3.5%	4.6	WI-I-Hemi_DVC	%	51.7 (2.0)	1.2	1.9	3.7%	5.4
FAZ Parameters (N=233)		**Retina Slab**											
FAZ Area	mm²	0.23 (0.089)	0.01	0.01	4.6%	0.03							
FAZ Perimeter	mm	1.8 (0.38)	0.1	0.1	3.4%	0.2							
FD-300 Vessel Density	%	48.4 (4.6)	2.9	3.9	8.0%	10.9							

Glaucoma Subjects

Superficial Vascular Complex (SVC)	Unit	N = 224					Deep Vascular Complex (DVC)	Unit	N = 224				
		Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*			Mean (SD)	Repeatability SD	Reproducibility SD	CV	Limit*
SVC		**ETDRS Grid (Ø 6mm)**					**DVC**		**ETDRS Grid (Ø 6mm)**				
C(1)_SVC	%	27.3 (6.0)	2.4	2.7	10.0%	7.7	C(1)_DVC	%	31.6 (7.0)	3.2	3.6	11.2%	9.9
T(1-3)_SVC	%	46.3 (3.2)	2.3	2.9	6.2%	8.1	T(1-3)_DVC	%	53.0 (1.9)	1.8	1.9	3.5%	5.2
S(1-3)_SVC	%	47.4 (3.3)	2.2	2.6	5.5%	7.3	S(1-3)_DVC	%	52.7 (2.4)	2.3	2.4	4.5%	6.6
N(1-3)_SVC	%	46.5 (3.3)	2.3	2.8	5.9%	7.7	N(1-3)_DVC	%	52.7 (2.6)	2.4	2.5	4.7%	6.9
I(1-3)_SVC	%	47.4 (3.4)	2.1	2.6	5.5%	7.3	I(1-3)_DVC	%	52.7 (2.1)	1.9	2.0	3.8%	5.6
S-Hemi(1-3)_SVC	%	46.9 (2.9)	1.9	2.4	5.1%	6.7	S-Hemi(1-3)_DVC	%	52.9 (2.0)	1.9	1.9	3.7%	5.5
I-Hemi(1-3)_SVC	%	47.0 (2.8)	1.8	2.3	4.8%	6.3	I-Hemi(1-3)_DVC	%	52.7 (1.7)	1.6	1.7	3.1%	4.6
All(1-3)_SVC	%	46.9 (2.7)	1.6	2.2	4.6%	6.0	All(1-3)_DVC	%	52.8 (1.4)	1.2	1.3	2.5%	3.8
T(3-6)_SVC	%	42.7 (2.7)	1.6	2.1	4.9%	5.9	T(3-6)_DVC	%	52.2 (2.2)	2.0	2.1	4.1%	6.0
S(3-6)_SVC	%	45.9 (2.7)	1.4	1.7	3.7%	4.7	S(3-6)_DVC	%	51.2 (2.6)	2.2	2.4	4.7%	6.7
N(3-6)_SVC	%	49.4 (2.5)	1.3	1.7	3.4%	4.8	N(3-6)_DVC	%	51.0 (3.0)	2.4	2.6	5.2%	7.4
I(3-6)_SVC	%	43.6 (3.8)	1.4	1.7	4.0%	4.9	I(3-6)_DVC	%	51.1 (3.2)	2.5	2.9	5.7%	8.2
S-Hemi(3-6)_SVC	%	46.2 (2.3)	1.3	1.7	3.6%	4.7	S-Hemi(3-6)_DVC	%	51.5 (2.2)	1.7	1.9	3.7%	5.4
I-Hemi(3-6)_SVC	%	44.6 (2.9)	1.2	1.6	3.5%	4.4	I-Hemi(3-6)_DVC	%	51.3 (2.5)	1.9	2.3	4.4%	6.4
All(3-6)_SVC	%	45.4 (2.1)	1.2	1.5	3.4%	4.3	All(3-6)_DVC	%	51.4 (2.0)	1.3	1.7	3.4%	4.8
All(0-6)_SVC	%	45.2 (2.0)	1.2	1.6	3.5%	4.4	All(0-6)_DVC	%	51.2 (1.6)	1.1	1.4	2.8%	3.9
SVC		**6 mm x 6 mm**					**DVC**		**6 mm x 6 mm**				
WI_SVC	%	45.3 (2.1)	1.1	1.5	3.4%	4.3	WI_DVC	%	50.6 (1.9)	1.1	1.5	3.0%	4.3
WI-S-Hemi_SVC	%	46.0 (2.1)	1.2	1.6	3.6%	4.6	WI-S-Hemi_DVC	%	50.8 (2.0)	1.3	1.7	3.3%	4.7
WI-I-Hemi_SVC	%	44.6 (2.8)	1.1	1.6	3.5%	4.4	WI-I-Hemi_DVC	%	50.5 (2.2)	1.5	1.9	3.8%	5.3
FAZ Parameters (N=215)		**Retina Slab**											
FAZ Area	mm²	0.26 (0.12)	0.01	0.01	4.5%	0.03							
FAZ Perimeter	mm	2.0 (0.51)	0.1	0.1	5.4%	0.3							
FD-300 Vessel Density	%	44.8 (5.4)	3.2	3.7	8.2%	10.3							

Retina Subjects												
Superficial Vascular Complex (SVC)	Unit	N = 252					Deep Vascular Complex (DVC)	Unit	N = 252				
		Mean (SD)	Repeatability SD	Reproducibility					Mean (SD)	Repeatability SD	Reproducibility		
				SD	CV	Limit*					SD	CV	Limit*
SVC		**ETDRS Grid (Ø 6mm)**					**DVC**		**ETDRS Grid (Ø 6mm)**				
C(1)_SVC	%	26.8 (5.2)	2.3	3.0	11.1%	8.4	C(1)_DVC	%	29.7 (6.1)	3.2	3.8	12.8%	10.6
T(1-3)_SVC	%	45.6 (3.0)	1.7	2.2	4.8%	6.2	T(1-3)_DVC	%	52.7 (2.2)	1.7	2.0	3.8%	5.6
S(1-3)_SVC	%	46.3 (3.2)	1.9	2.5	5.4%	6.9	S(1-3)_DVC	%	52.8 (2.7)	2.3	2.5	4.7%	6.9
N(1-3)_SVC	%	45.2 (3.4)	2.0	2.6	5.7%	7.1	N(1-3)_DVC	%	52.4 (3.0)	2.2	2.6	5.0%	7.4
I(1-3)_SVC	%	46.5 (3.1)	1.8	2.4	5.1%	6.6	I(1-3)_DVC	%	52.9 (2.0)	1.8	1.9	3.5%	5.2
S-Hemi(1-3)_SVC	%	45.8 (2.8)	1.6	2.2	4.8%	6.1	S-Hemi(1-3)_DVC	%	52.6 (2.3)	1.6	1.9	3.5%	5.2
I-Hemi(1-3)_SVC	%	46.0 (2.9)	1.5	2.0	4.4%	5.7	I-Hemi(1-3)_DVC	%	52.8 (1.8)	1.4	1.6	3.1%	4.6
All(1-3)_SVC	%	45.9 (2.7)	1.4	2.0	4.3%	5.5	All(1-3)_DVC	%	52.7 (1.7)	1.2	1.4	2.7%	4.0
T(3-6)_SVC	%	43.1 (2.4)	1.4	2.0	4.7%	5.7	T(3-6)_DVC	%	52.5 (2.3)	1.8	2.1	3.9%	5.8
S(3-6)_SVC	%	46.4 (2.3)	1.4	1.6	3.4%	4.4	S(3-6)_DVC	%	51.9 (2.5)	1.9	2.1	4.0%	5.9
N(3-6)_SVC	%	49.6 (2.1)	1.5	1.6	3.3%	4.6	N(3-6)_DVC	%	51.4 (2.5)	2.0	2.2	4.2%	6.1
I(3-6)_SVC	%	45.9 (2.7)	1.3	1.6	3.4%	4.4	I(3-6)_DVC	%	51.0 (3.3)	2.2	2.4	4.7%	6.8
S-Hemi(3-6)_SVC	%	46.3 (1.9)	1.3	1.6	3.4%	4.3	S-Hemi(3-6)_DVC	%	52.1 (2.0)	1.4	1.7	3.2%	4.6
I-Hemi(3-6)_SVC	%	46.3 (2.3)	1.2	1.5	3.2%	4.2	I-Hemi(3-6)_DVC	%	51.2 (2.7)	1.7	1.9	3.7%	5.4
All(3-6)_SVC	%	46.3 (1.9)	1.2	1.5	3.1%	4.1	All(3-6)_DVC	%	51.7 (1.9)	1.2	1.4	2.8%	4.0
All(0-6)_SVC	%	45.6 (1.8)	1.2	1.5	3.2%	4.1	All(0-6)_DVC	%	51.3 (1.6)	1.0	1.2	2.3%	3.4
SVC		**6 mm x 6 mm**					**DVC**		**6 mm x 6 mm**				
WI_SVC	%	46.3 (1.9)	1.1	1.4	3.0%	3.9	WI_DVC	%	50.7 (1.9)	1.0	1.5	2.9%	4.1
WI-S-Hemi_SVC	%	46.3 (1.9)	1.2	1.5	3.1%	4.1	WI-S-Hemi_DVC	%	51.1 (1.9)	1.2	1.6	3.2%	4.6
WI-I-Hemi_SVC	%	46.2 (2.0)	1.1	1.4	3.0%	3.9	WI-I-Hemi_DVC	%	50.3 (2.5)	1.4	1.8	3.5%	4.9
FAZ Parameters (N=252)		**Retina Slab**											
FAZ Area	mm^2	0.35 (0.22)	0.01	0.02	5.2%	0.05							
FAZ Perimeter	mm	2.4 (1.1)	0.1	0.1	5.3%	0.4							
FD-300 Vessel Density	%	45.3 (5.3)	2.7	4.0	8.7%	11.1							

Structural Parameters of the Disc Scans – R&R Results

Normal Subjects											
Measurement	Unit	AngioVue Disc (N=270)					Disc Cube (N=270)				
		Mean (SD)	Repeatability SD	Reproducibility			Mean (SD)	Repeatability SD	Reproducibility		
				SD	CV	Limit*			SD	CV	Limit*
RNFL		**Ø2.5 ~ Ø4.5 mm Ring**									
TS_RNFL	μm	62.5 (8.1)	1.0	1.9	3.1%	5.4	62.8 (8.0)	1.2	1.9	3.0%	5.3
ST_RNFL	μm	114.5 (17.2)	1.3	2.7	2.4%	7.6	111.8 (16.3)	1.5	2.7	2.4%	7.5
SN_RNFL	μm	109.8 (25.5)	1.1	1.9	1.8%	5.4	109.8 (25.0)	1.7	2.3	2.1%	6.6
NS_RNFL	μm	90.4 (15.8)	0.7	1.7	1.9%	4.8	90.3 (15.7)	1.4	2.1	2.3%	5.9
NI_RNFL	μm	70.9 (12.0)	0.9	2.0	2.9%	5.7	71.3 (12.3)	1.3	2.2	3.1%	6.2
IN_RNFL	μm	111.4 (19.5)	1.0	2.1	1.9%	5.9	111.0 (19.4)	1.6	2.6	2.3%	7.2
IT_RNFL	μm	132.7 (16.2)	1.1	2.6	2.0%	7.3	129.5 (15.5)	1.7	3.0	2.3%	8.4
TI_RNFL	μm	56.0 (7.5)	0.8	1.8	3.1%	4.9	56.6 (8.0)	1.3	2.3	4.0%	6.4
T_RNFL	μm	59.5 (7.1)	0.8	1.5	2.5%	4.2	59.9 (7.3)	1.0	1.6	2.6%	4.4
S_RNFL	μm	111.9 (16.2)	0.9	1.6	1.4%	4.3	110.7 (16.4)	1.2	1.8	1.6%	5.1
N_RNFL	μm	81.7 (12.9)	0.6	1.6	2.0%	4.5	81.8 (13.1)	1.0	1.7	2.0%	4.6
I_RNFL	μm	120.8 (14.0)	0.8	1.3	1.1%	3.7	119.1 (14.2)	1.2	1.7	1.5%	4.8
S-Hemi_RNFL	μm	93.0 (11.3)	0.5	1.0	1.1%	2.9	92.5 (11.4)	0.8	1.1	1.2%	3.0
I-Hemi_RNFL	μm	92.0 (10.2)	0.5	0.9	1.0%	2.6	91.4 (10.4)	0.8	1.1	1.3%	3.2
PP_RNFL	μm	92.5 (9.9)	0.4	0.9	0.9%	2.4	92.0 (10.1)	0.6	0.9	1.0%	2.5
ONH Parameters		**Within Disc Margin**									
Cup Area	mm^2	0.36 (0.28)	0.010	0.015	4.2%	0.042	0.33 (0.28)	0.018	0.024	7.1%	0.067
Rim Area	mm^2	1.4 (0.27)	0.012	0.064	4.7%	0.180	1.4 (0.28)	0.019	0.065	4.7%	0.180
C-D_Area_Ratio		0.20 (0.14)	0.006	0.011	5.8%	0.032	0.19 (0.14)	0.010	0.014	7.8%	0.040
C-D_H_Ratio		0.41 (0.22)	0.015	0.024	5.9%	0.068	0.39 (0.23)	0.020	0.024	6.3%	0.068
C-D_V_Ratio		0.39 (0.21)	0.011	0.021	5.3%	0.058	0.37 (0.22)	0.018	0.023	6.1%	0.063
CupVolume	mm^3	0.073 (0.085)	0.004	0.005	6.8%	0.014	0.065 (0.084)	0.007	0.012	18.5%	0.034
DiscArea	mm^2	1.7 (0.32)	0.003	0.064	3.8%	0.180	1.7 (0.32)	0.002	0.064	3.8%	0.180

Measurement	Unit	AngioVue Disc (N=225)					Disc Cube (N=225)				
			Repeatability	Reproducibility				Repeatability	Reproducibility		
		Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*
RNFL					Ø2.5 ~ Ø4.5 mm Ring						
TS_RNFL	µm	54.3 (13.2)	1.0	1.5	2.7%	4.1	54.0 (13.1)	1.2	1.5	2.8%	4.3
ST_RNFL	µm	76.1 (31.0)	1.2	2.1	2.8%	6.0	73.4 (29.5)	1.3	2.4	3.2%	6.6
SN_RNFL	µm	71.1 (22.1)	1.0	1.7	2.3%	4.7	70.4 (22.1)	1.7	2.5	3.6%	7.1
NS_RNFL	µm	58.4 (17.5)	1.2	1.7	2.9%	4.8	58.5 (17.0)	1.8	2.1	3.7%	6.0
NI_RNFL	µm	49.7 (12.6)	1.1	1.4	2.8%	3.9	49.9 (12.6)	1.7	1.9	3.7%	5.2
IN_RNFL	µm	73.4 (23.4)	1.1	1.9	2.6%	5.4	72.4 (24.0)	1.8	2.2	3.1%	6.2
IT_RNFL	µm	76.7 (31.7)	0.9	2.0	2.6%	5.7	74.3 (30.5)	1.5	2.1	2.8%	5.8
TI_RNFL	µm	46.7 (9.6)	0.8	1.3	2.8%	3.7	46.5 (9.9)	1.7	2.0	4.3%	5.5
T_RNFL	µm	50.8 (10.6)	0.8	1.2	2.3%	3.3	50.5 (10.7)	1.2	1.4	2.9%	4.0
S_RNFL	µm	73.3 (23.1)	0.9	1.2	1.6%	3.3	71.8 (23.0)	1.1	1.9	2.6%	5.2
N_RNFL	µm	54.5 (14.5)	1.0	1.3	2.3%	3.5	54.7 (14.3)	1.5	1.7	3.0%	4.6
I_RNFL	µm	74.8 (25.7)	0.9	1.7	2.2%	4.7	73.2 (25.7)	1.4	1.7	2.3%	4.8
S-Hemi_RNFL	µm	63.9 (16.3)	0.7	0.8	1.3%	2.3	63.1 (16.4)	0.9	1.2	1.9%	3.4
I-Hemi_RNFL	µm	61.3 (16.4)	0.7	0.9	1.5%	2.6	60.5 (16.5)	0.9	1.1	1.8%	3.0
PP_RNFL	µm	62.6 (14.5)	0.6	0.7	1.2%	2.0	61.9 (14.7)	0.8	1.0	1.6%	2.7
ONH Parameters					Within Disc Margin						
Cup Area	mm²	1.1 (0.53)	0.043	0.043	3.8%	0.120	1.1 (0.54)	0.035	0.048	4.2%	0.130
Rim Area	mm²	0.69 (0.32)	0.047	0.071	10.3%	0.200	0.67 (0.32)	0.037	0.079	11.7%	0.220
C-D_Area_Ratio		0.60 (0.21)	0.021	0.026	4.4%	0.074	0.61 (0.21)	0.019	0.031	5.1%	0.087
C-D_H_Ratio		0.77 (0.21)	0.016	0.024	3.2%	0.068	0.78 (0.21)	0.029	0.037	4.7%	0.100
C-D_V_Ratio		0.77 (0.20)	0.019	0.024	3.2%	0.068	0.76 (0.21)	0.026	0.036	4.7%	0.100
CupVolume	mm³	0.29 (0.17)	0.013	0.016	5.4%	0.043	0.28 (0.17)	0.020	0.025	8.7%	0.069
DiscArea	mm²	1.8 (0.40)	0.004	0.069	3.8%	0.190	1.8 (0.40)	0.003	0.069	3.8%	0.190

Glaucoma Subjects (table title above)

Measurement	Unit	AngioVue Disc (N=252)					Disc Cube (N=252)				
			Repeatability	Reproducibility				Repeatability	Reproducibility		
		Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*
RNFL					Ø2.5 ~ Ø4.5 mm Ring						
TS_RNFL	µm	64.1 (14.4)	1.4	2.2	3.5%	6.3	64.1 (14.1)	1.4	2.0	3.1%	5.5
ST_RNFL	µm	106.8 (27.8)	1.5	2.8	2.6%	7.9	104.2 (27.1)	2.1	3.3	3.1%	9.1
SN_RNFL	µm	101.5 (27.3)	1.3	2.7	2.6%	7.5	100.0 (26.7)	2.3	3.0	3.0%	8.5
NS_RNFL	µm	84.9 (19.9)	1.4	2.2	2.6%	6.2	85.1 (19.7)	2.1	2.4	2.8%	6.7
NI_RNFL	µm	69.0 (15.8)	1.2	2.1	3.1%	5.9	69.0 (15.9)	1.9	2.3	3.3%	6.4
IN_RNFL	µm	107.7 (24.7)	1.6	2.7	2.5%	7.5	106.7 (25.1)	2.2	2.9	2.7%	8.1
IT_RNFL	µm	123.6 (22.1)	2.0	3.2	2.6%	8.9	119.6 (22.3)	2.3	3.7	3.1%	10.5
TI_RNFL	µm	58.4 (11.9)	1.0	1.9	3.3%	5.3	58.4 (11.5)	1.2	2.1	3.6%	5.8
T_RNFL	µm	61.5 (12.7)	1.1	1.6	2.6%	4.4	61.5 (12.3)	1.1	1.4	2.3%	3.9
S_RNFL	µm	103.9 (23.0)	1.0	2.2	2.1%	6.2	101.9 (22.8)	1.8	2.7	2.6%	7.5
N_RNFL	µm	77.8 (17.2)	1.1	1.7	2.2%	4.8	77.9 (17.1)	1.5	1.8	2.3%	5.0
I_RNFL	µm	114.7 (20.2)	1.2	1.7	1.5%	4.8	112.4 (20.9)	1.7	2.1	1.8%	5.8
S-Hemi_RNFL	µm	88.2 (15.8)	0.8	1.5	1.7%	4.3	87.3 (15.7)	1.3	1.6	1.9%	4.6
I-Hemi_RNFL	µm	89.0 (14.2)	0.7	1.1	1.3%	3.2	87.9 (14.4)	1.0	1.3	1.5%	3.6
PP_RNFL	µm	88.6 (14.3)	0.7	1.2	1.4%	3.4	87.6 (14.4)	0.9	1.3	1.4%	3.5
ONH Parameters					Within Disc Margin						
Cup Area	mm²	0.38 (0.30)	0.013	0.018	4.7%	0.051	0.37 (0.30)	0.016	0.020	5.5%	0.057
Rim Area	mm²	1.4 (0.41)	0.014	0.072	5.2%	0.200	1.4 (0.41)	0.018	0.074	5.3%	0.210
C-D_Area_Ratio		0.22 (0.17)	0.008	0.014	6.4%	0.039	0.21 (0.17)	0.009	0.015	7.1%	0.042
C-D_H_Ratio		0.41 (0.24)	0.014	0.022	5.4%	0.062	0.39 (0.25)	0.022	0.027	7.0%	0.077
C-D_V_Ratio		0.41 (0.27)	0.011	0.017	4.2%	0.049	0.41 (0.27)	0.023	0.027	6.5%	0.074
CupVolume	mm³	0.065 (0.075)	0.003	0.004	6.3%	0.011	0.060 (0.068)	0.012	0.012	19.7%	0.033
DiscArea	mm²	1.8 (0.30)	0.003	0.069	3.9%	0.190	1.8 (0.30)	0.002	0.069	3.9%	0.190

Retina Subjects (table title above)

Vascular Parameters of the Disc Scan – R&R Results

AngioVue Disc	Unit	Normal Subjects (N=270)					Glaucoma Subjects (N=225)					Retina Subjects (N=252)				
			Repeatability	Reproducibility				Repeatability	Reproducibility				Repeatability	Reproducibility		
		Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*	Mean (SD)	SD	SD	CV	Limit*
RPC Vessel Density		Ø2.5 ~ Ø4.5 mm Ring														
TS_RPC_Sml	%	56.2 (3.9)	1.6	2.0	3.6%	5.6	53.8 (6.4)	1.9	2.5	4.7%	7.1	56.0 (4.3)	2.1	2.3	4.2%	6.5
ST_RPC_Sml	%	52.5 (4.4)	1.9	2.1	4.1%	6.0	42.1 (10.4)	2.2	2.8	6.6%	7.8	49.0 (6.3)	2.3	2.5	5.2%	7.1
SN_RPC_Sml	%	46.1 (4.2)	1.8	2.3	5.0%	6.4	38.6 (7.8)	2.2	2.6	6.6%	7.2	43.4 (5.7)	2.2	2.5	5.7%	6.9
NS_RPC_Sml	%	46.5 (4.0)	1.5	1.9	4.1%	5.3	37.2 (5.6)	2.0	2.8	7.6%	7.9	44.7 (4.8)	1.9	2.4	5.3%	6.6
NI_RPC_Sml	%	46.2 (3.8)	1.7	2.0	4.3%	5.5	39.8 (6.1)	2.9	3.2	8.0%	8.9	44.8 (5.4)	2.1	2.2	4.8%	6.1
IN_RPC_Sml	%	46.0 (4.5)	1.6	2.0	4.3%	5.5	37.7 (8.5)	2.4	3.2	8.5%	9.0	44.7 (5.5)	2.6	3.2	7.2%	9.0
IT_RPC_Sml	%	55.0 (3.2)	1.7	2.2	3.9%	6.0	44.1 (9.9)	2.2	2.7	6.0%	7.4	52.5 (4.8)	2.5	2.8	5.4%	7.9
TI_RPC_Sml	%	53.3 (4.1)	1.7	1.9	3.6%	5.4	49.7 (5.4)	2.0	2.5	5.1%	7.0	53.4 (3.9)	2.2	2.4	4.5%	6.7
S-Hemi_RPC_Sml	%	50.1 (3.1)	1.3	1.5	2.9%	4.1	42.7 (5.9)	1.4	2.0	4.8%	5.7	48.1 (3.9)	1.6	1.8	3.8%	5.1
I-Hemi_RPC_Sml	%	49.7 (3.1)	1.1	1.3	2.7%	3.8	42.5 (5.8)	1.8	2.1	5.0%	5.9	48.5 (3.6)	1.6	1.8	3.7%	5.0
PP_RPC_Sml	%	49.9 (2.9)	1.1	1.3	2.6%	3.6	42.6 (5.2)	1.5	1.9	4.5%	5.4	48.3 (3.5)	1.5	1.7	3.4%	4.7
S-Hemi_RPC_All	%	56.5 (3.0)	1.1	1.2	2.1%	3.3	49.7 (5.5)	1.2	1.7	3.3%	4.6	54.5 (3.7)	1.3	1.5	2.7%	4.1
I-Hemi_RPC_All	%	55.9 (3.0)	1.0	1.1	1.9%	3.0	49.0 (5.2)	1.6	1.8	3.7%	5.1	54.3 (3.6)	1.4	1.5	2.8%	4.2
PP_RPC_All	%	56.2 (2.8)	1.0	1.0	1.9%	2.9	49.3 (4.8)	1.3	1.6	3.2%	4.5	54.4 (3.5)	1.3	1.4	2.5%	3.8
RPC Vessel Density		6 mm x 6 mm														
WI_RPC_Sml	%	47.5 (2.7)	0.9	1.2	2.5%	3.3	41.6 (4.1)	1.3	1.8	4.3%	5.0	46.6 (2.9)	1.1	1.4	3.0%	4.0
WI_RPC_All	%	53.7 (2.6)	0.9	1.2	2.2%	3.4	48.2 (3.7)	1.2	1.6	3.3%	4.4	52.7 (2.8)	1.0	1.3	2.5%	3.6

OCTA vessel density measurements – agreement with the Avanti XR predicate device

For both the superficial and deep vascular complexes imaged with the macular AngioVue scans, the vessel density values from SOLIX tended to be within a smaller range than the vessel density values from Avanti XR (e.g., absolute values of SOLIX vs. Avanti XR Deming regression slopes are less than 1). For the radial peripapillary capillaries imaged with disc scans, vessel density measurement agreement between SOLIX and Avanti XR was closer than what was observed with macular AngioVue scans. Differences between SOLIX and Avanti XR vessel density measurements are associated with the increased scan density (due to smaller OCTA image pixel size) with SOLIX and updates to the vessel density software algorithm in SOLIX.

Solix Fundus Photography

This was a prospective, observational study conducted at two clinical sites. Eligible participants were assigned to either the "normal," glaucoma, or retinal disease sub-group. Three SOLIX and three iCam devices were paired with three designated operators to form three SOLIX-iCAM-operator configurations. Every participant was imaged with one configuration (two repeated images per camera). The eligibility criteria were very similar to those used in the study conducted to evaluate repeatability and reproducibility. Of 126 participants were enrolled, 121 met enrollment criteria, and data from 112 was included in the dataset (31 "normal," 26 glaucoma, 55 retinal disease). Images were graded by three independent graders at a third-party reading center for image quality and clinical utility based on pre-specified grading criteria . The proportions of SOLIX images graded as similar or better quality compared to iCAM images ranged from 74-89% across sub-groups and graders. The proportion of participants with clinically useful images was the same for both SOLIX and iCam at 97.3%.

Solix RDB

This was a prospective, observational study conducted at five U.S. clinical sites. The key eligibility criteria included participants age ≥18 with no history of ocular pathology or treatment, and no signs of ocular pathology based on clinical examination, fundus photography, and visual field testing. Retinal pathologies (except hard drusen or non-significant incidental findings),

glaucomatous optic nerve damage or visual field (VF) abnormalities, best-corrected visual acuity (BCVA) worse than 20/40, intraocular pressure (IOP) >21 mm Hg, and unreliable VF testing results were exclusion criteria. Individuals with history of systemic conditions potentially affecting the eye, such as hydroxychloroquine or chloroquine use, leukemia, dementia or multiple sclerosis were excluded. Only one eye per eligible participant was included in the RDB dataset. If both eyes qualified, then one eye was randomly selected as the study eye for RDB inclusion. Reference limits at the 1st, 5th, 95th and 99th percentiles were estimated with quantile regression analysis. Age and/or disc size were used as regression covariates.

Results

482 participants were enrolled and 427 were determined to be eligible. The number of participants included into the RDB for each scan pattern ranged from 416 to 426. The mean age was 48.2 to 48.3 years (range 18 to 89 years). 56.7% (242/427) of the cohort are women and 43.3% (185/427) are men. 63.7% are Caucasian, 13.1% are African-American, 11.5% are Asian, 7.3% are American Indian/Alaskan, 1.2% are multiracial, 1.2% are designated as "other" race, and race was not reported in 2.1%. 15.2% was reported as being of Hispanic, Latino, and/or Spanish origin. The median best-corrected Snellen visual acuity (BCVA) was 20/20 (range 20/13 to 20/40). The mean refractive error (manifest refraction-based spherical error [MRSE]) was -0.87±1.91 D (range -7.75 to +3.00 D). The mean axial length (AL) was 23.97±1.20 mm (range 20.11 to 28.30 mm).

Scans from all included participants underwent post-acquisition image quality review. OCT and OCTA scans with a SQ score of less than 6, local weak signal affecting regional structure and/or vasculature visibility, motion artifacts, blink, and cropped B-scan images etc. were excluded from analysis. Five scan patterns were evaluated, three macular scans (AngioVue Retina, Retina Cube and Wellness), and two disc-based scans (AngioVue Disc and Disc Cube). For the macular scan patterns, the rate of disqualified scans was less than 5% for all scan patterns, and for the disc-based scans, the rate of disqualified scans was less than 4% for AngioVue Disc scan and less than 15% for Disc Cube scan, mainly due to eye motion during image acquisition. There was no segmentation boundary editing for any of the qualified scans included in the RDB data set for any of the 5 scan patterns. There was no manual adjustment of fovea center for ETDRS grid placement. Disc margin manual correction was performed for the baseline scan. The Bruch's membrane opening (BMO) editing rate was about 8%.

Race	Subject #	%
African American	56	13.1 %
Asian	49	11.5 %
Caucasian	272	63.7 %
Pacific Islander	0	0.0%
American Indian	31	7.3%
Multiracial	5	1.2 %
Other	5	1.2 %
Not Disclosed	9	2.1 %
Total	427	
Ethnicity	Subject #	%
Hispanic	65	15.2
Non-Hispanic	359	84.1 %
Not Disclosed	3	0.7 %
Total	427	

Variables Summary by Scan Type

For each scan type, the table below summarizes the variables distribution

Factor Level	Solix AngioVue Retina	Solix Retina Cube	Solix Wellness
N (subjects)	426	424	423
C(1)_GCC			
Mean(SD)	56.3 (10.2)	56.5 (10.4)	62.6 (10.3)
Median	55.4	55.7	61.9
Min, Max	[30.8, 85.7]	[31.5, 86.9]	[36.8, 89.7]
T(1-3)_GCC			
Mean(SD)	102.6 (7.7)	103.5 (7.7)	102.5 (7.5)
Median	102.4	103.2	102.0
Min, Max	[78.3, 126.5]	[78.0, 127.9]	[77.8, 126.3]
S(1-3)_GCC			
Mean(SD)	114.2 (8.4)	113.7 (8.5)	111.8 (8.5)
Median	113.6	113.3	111.4
Min, Max	[85.9, 138.7]	[85.9, 137.5]	[85.0, 135.1]
N(1-3)_GCC			
Mean(SD)	111.4 (8.8)	111.8 (8.9)	111.0 (8.7)
Median	111.2	111.6	110.7
Min, Max	[81.5, 138.0]	[81.1, 140.1]	[81.1, 137.8]
I(1-3)_GCC			
Mean(SD)	115.2 (8.3)	114.5 (8.5)	111.8 (8.4)
Median	115.1	114.7	111.3
Min, Max	[86.5, 138.5]	[84.1, 138.3]	[81.7, 136.8]
S-Hemi(1-3)_GCC			
Mean(SD)	110.1 (8.2)	110.2 (8.2)	109.5 (8.0)
Median	109.7	109.9	108.8
Min, Max	[82.4, 134.5]	[82.7, 134.3]	[82.6, 130.8]
I-Hemi(1-3)_GCC			
Mean(SD)	111.5 (8.1)	111.5 (8.2)	110.0 (7.9)
Median	111.4	111.2	109.8
Min, Max	[83.7, 133.1]	[81.8, 133.4]	[81.0, 132.1]
All(1-3)_GCC			
Mean(SD)	110.8 (8.0)	110.9 (8.1)	109.7 (7.8)
Median	110.5	110.5	109.1
Min, Max	[83.0, 132.9]	[82.3, 133.3]	[81.8, 130.4]
T(3-6)_GCC			
Mean(SD)	85.6 (6.6)	86.1 (6.6)	81.6 (6.4)

Factor Level	Solix AngioVue Retina	Solix Retina Cube	Solix Wellness
Median	85.5	85.8	81.2
Min, Max	[63.4, 105.4]	[63.8, 106.1]	[59.3, 100.9]
S(3-6)_GCC			
Mean(SD)	100.8 (8.3)	99.6 (8.3)	91.9 (8.6)
Median	100.3	99.3	91.5
Min, Max	[73.7, 125.3]	[71.8, 123.2]	[64.7, 120.2]
N(3-6)_GCC			
Mean(SD)	117.3 (9.7)	116.6 (9.8)	113.1 (10.2)
Median	117.5	116.8	113.3
Min, Max	[83.2, 147.4]	[83.6, 148.3]	[78.8, 146.7]
I(3-6)_GCC			
Mean(SD)	100.3 (8.4)	99.1 (8.4)	95.0 (9.4)
Median	100.0	98.6	95.0
Min, Max	[70.7, 126.9]	[69.4, 125.6]	[65.2, 123.2]
S-Hemi(3-6)_GCC			
Mean(SD)	100.5 (7.7)	99.9 (7.8)	93.6 (7.8)
Median	100.1	99.5	93.2
Min, Max	[74.0, 123.0]	[73.1, 121.5]	[67.2, 119.5]
I-Hemi(3-6)_GCC			
Mean(SD)	101.5 (8.0)	100.8 (8.0)	96.6 (8.5)
Median	101.5	100.8	96.5
Min, Max	[72.6, 126.5]	[72.1, 126.1]	[67.4, 122.9]
All(3-6)_GCC			
Mean(SD)	101.0 (7.6)	100.4 (7.6)	95.1 (7.8)
Median	100.7	100.2	94.9
Min, Max	[75.8, 122.4]	[75.1, 122.1]	[69.4, 116.2]
S-Hemi(0-6)_GCC			
Mean(SD)	101.4 (7.3)	101.0 (7.4)	96.2 (7.4)
Median	100.9	100.3	95.9
Min, Max	[75.9, 124.3]	[75.2, 123.1]	[70.5, 121.1]
I-Hemi(0-6)_GCC			
Mean(SD)	102.5 (7.5)	102.0 (7.5)	98.6 (7.9)
Median	102.5	102.1	98.8
Min, Max	[75.7, 124.2]	[74.8, 123.9]	[70.1, 122.3]
All(0-6)_GCC			
Mean(SD)	101.9 (7.2)	101.5 (7.2)	97.4 (7.4)
Median	101.5	101.0	96.9
Min, Max	[77.5, 122.3]	[76.6, 122.1]	[71.3, 118.0]

Factor Level	Solix AngioVue Retina	Solix Retina Cube	Solix Wellness
C(1)_R			
Mean(SD)	259.2 (21.7)	259.1 (21.9)	257.8 (21.9)
Median	258.9	258.9	257.8
Min, Max	[201.0, 325.5]	[202.6, 325.6]	[194.5, 327.5]
T(1-3)_R			
Mean(SD)	315.3 (14.4)	316.0 (14.3)	314.3 (14.5)
Median	315.2	316.1	313.5
Min, Max	[278.5, 372.1]	[281.8, 370.8]	[276.3, 371.8]
S(1-3)_R			
Mean(SD)	328.6 (14.6)	329.1 (14.4)	326.7 (14.9)
Median	327.9	328.3	326.3
Min, Max	[287.7, 377.5]	[287.4, 378.2]	[281.7, 377.3]
N(1-3)_R			
Mean(SD)	329.5 (14.8)	329.9 (14.9)	326.9 (15.0)
Median	329.5	329.9	327.2
Min, Max	[289.6, 376.1]	[290.3, 374.8]	[283.7, 375.9]
I(1-3)_R			
Mean(SD)	324.2 (14.1)	324.6 (14.1)	323.7 (14.4)
Median	324.1	324.4	324.1
Min, Max	[286.5, 368.9]	[289.5, 368.1]	[281.3, 369.1]
S-Hemi(1-3)_R			
Mean(SD)	325.4 (14.4)	325.9 (14.3)	323.4 (14.6)
Median	325.2	326.0	323.1
Min, Max	[285.2, 375.6]	[286.7, 375.6]	[280.3, 375.0]
I-Hemi(1-3)_R			
Mean(SD)	323.4 (14.0)	323.8 (14.1)	322.4 (14.2)
Median	323.2	323.6	322.1
Min, Max	[285.9, 370.3]	[289.0, 370.2]	[281.3, 370.1]
All(1-3)_R			
Mean(SD)	324.4 (14.1)	324.9 (14.0)	322.9 (14.3)
Median	324.4	324.8	322.9
Min, Max	[285.6, 372.9]	[287.9, 372.9]	[280.8, 372.6]
T(3-6)_R			
Mean(SD)	266.9 (13.1)	268.4 (13.3)	279.0 (14.1)
Median	267.0	268.4	279.3
Min, Max	[227.1, 310.2]	[229.4, 310.6]	[240.9, 325.1]
S(3-6)_R			
Mean(SD)	284.4 (13.5)	285.2 (13.4)	292.5 (14.3)

Factor Level	Solix AngioVue Retina	Solix Retina Cube	Solix Wellness
Median	283.7	284.9	291.8
Min, Max	[244.5, 322.8]	[245.7, 320.5]	[249.7, 336.3]
N(3-6)_R			
Mean(SD)	299.8 (14.9)	300.7 (14.9)	302.1 (15.6)
Median	299.8	300.7	302.9
Min, Max	[257.5, 336.8]	[259.2, 338.7]	[257.5, 341.7]
I(3-6)_R			
Mean(SD)	270.9 (13.1)	271.4 (13.3)	281.0 (14.5)
Median	270.9	271.6	281.7
Min, Max	[234.4, 311.0]	[232.9, 312.9]	[239.5, 325.9]
S-Hemi(3-6)_R			
Mean(SD)	284.3 (13.3)	285.3 (13.3)	291.7 (14.1)
Median	284.1	285.1	291.2
Min, Max	[243.8, 321.8]	[245.1, 321.6]	[250.3, 331.5]
I-Hemi(3-6)_R			
Mean(SD)	276.7 (13.1)	277.5 (13.2)	285.6 (14.2)
Median	276.7	277.9	286.2
Min, Max	[238.0, 314.8]	[238.5, 316.7]	[243.5, 328.7]
All(3-6)_R			
Mean(SD)	280.5 (13.0)	281.4 (13.0)	288.6 (13.9)
Median	280.6	281.2	288.7
Min, Max	[240.9, 318.2]	[241.8, 317.7]	[246.9, 329.1]
S-Hemi(0-6)_R			
Mean(SD)	292.8 (12.9)	293.6 (12.9)	297.8 (13.6)
Median	292.5	293.1	297.2
Min, Max	[251.8, 332.7]	[253.2, 333.1]	[255.4, 339.1]
I-Hemi(0-6)_R			
Mean(SD)	286.6 (12.6)	287.3 (12.7)	293.0 (13.5)
Median	286.5	286.9	293.1
Min, Max	[247.6, 322.3]	[248.7, 322.5]	[250.6, 331.7]
All(0-6)_R			
Mean(SD)	289.7 (12.6)	290.5 (12.6)	295.4 (13.4)
Median	289.1	290.4	295.1
Min, Max	[249.7, 327.5]	[251.0, 327.7]	[253.0, 335.4]
All(0-6)_R_Vol			
Mean(SD)	8.2 (0.4)	8.2 (0.4)	NA
Median	8.2	8.2	NA
Min, Max	[7.1, 9.3]	[7.1, 9.3]	

Factor Level	Solix AngioVue Retina	Solix Retina Cube	Solix Wellness
WI_GCC			
Mean(SD)	103.1 (7.4)	102.5 (7.5)	92.3 (6.8)
Median	102.8	102.2	92.0
Min, Max	[78.4, 124.7]	[77.4, 123.9]	[68.7, 109.7]
WI-S-Hemi_GCC			
Mean(SD)	102.0 (7.6)	101.5 (7.7)	91.4 (7.0)
Median	101.1	100.8	91.0
Min, Max	[76.6, 128.3]	[75.6, 126.9]	[67.5, 112.6]
WI-I-Hemi_GCC			
Mean(SD)	104.1 (7.8)	103.6 (7.9)	93.3 (7.2)
Median	104.3	103.7	93.3
Min, Max	[75.6, 126.5]	[75.4, 125.9]	[68.2, 116.3]

Factor Level	Solix AngioVue Disc	Solix Disc Cube
N (subjects)	423	416
TS_RNFL		
Mean(SD)	64.59 (10.22)	64.75 (10.04)
Median	63.90	64.50
Min, Max	[40.30, 112.70]	[39.40, 105.90]
ST_RNFL		
Mean(SD)	120.23 (20.41)	117.43 (19.50)
Median	119.80	116.75
Min, Max	[58.90, 169.20]	[59.30, 174.20]
SN_RNFL		
Mean(SD)	110.39 (21.10)	110.42 (20.55)
Median	109.10	108.80
Min, Max	[58.40, 174.30]	[59.80, 167.50]
NS_RNFL		
Mean(SD)	90.91 (14.88)	91.27 (14.57)
Median	91.40	92.15
Min, Max	[43.40, 136.40]	[49.80, 137.20]
NI_RNFL		
Mean(SD)	69.54 (13.76)	69.77 (13.73)
Median	69.90	69.50
Min, Max	[33.40, 127.20]	[35.80, 129.20]
IN_RNFL		
Mean(SD)	115.90 (23.12)	115.39 (22.76)

Factor Level	Solix AngioVue Disc	Solix Disc Cube
Median	114.30	114.00
Min, Max	[61.40, 193.80]	[61.30, 189.80]
IT_RNFL		
Mean(SD)	134.63 (19.99)	131.79 (19.67)
Median	134.70	132.60
Min, Max	[63.70, 194.00]	[64.60, 201.60]
TI_RNFL		
Mean(SD)	58.98 (11.98)	59.26 (11.82)
Median	57.70	57.90
Min, Max	[35.90, 140.50]	[35.70, 134.40]
T_RNFL		
Mean(SD)	62.01 (9.98)	62.21 (9.72)
Median	61.70	61.70
Min, Max	[39.20, 125.50]	[39.10, 114.80]
S_RNFL		
Mean(SD)	114.86 (13.88)	113.59 (13.94)
Median	115.70	113.95
Min, Max	[79.50, 155.60]	[77.90, 156.40]
N_RNFL		
Mean(SD)	81.40 (13.33)	81.71 (13.15)
Median	81.80	81.85
Min, Max	[38.90, 130.20]	[45.00, 130.90]
I_RNFL		
Mean(SD)	124.18 (16.03)	122.61 (16.10)
Median	123.60	121.65
Min, Max	[84.60, 176.20]	[82.30, 173.80]
S-Hemi_RNFL		
Mean(SD)	94.97 (9.86)	94.58 (9.87)
Median	95.30	95.25
Min, Max	[66.20, 118.30]	[67.30, 117.70]
I-Hemi_RNFL		
Mean(SD)	93.94 (10.67)	93.26 (10.77)
Median	94.10	93.40
Min, Max	[63.40, 122.80]	[62.70, 122.00]
PP_RNFL		
Mean(SD)	94.48 (9.73)	93.95 (9.78)
Median	94.60	94.10
Min, Max	[64.90, 118.40]	[65.20, 117.90]

Factor Level	Solix AngioVue Disc	Solix Disc Cube
DiscArea(mm2)		
Mean(SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]
CupArea(mm2)		
Mean(SD)	0.51 (0.35)	0.49 (0.35)
Median	0.46	0.43
Min, Max	[0.00, 2.24]	[0.00, 2.38]
RimArea(mm2)		
Mean(SD)	1.34 (0.30)	1.35 (0.31)
Median	1.32	1.32
Min, Max	[0.57, 2.33]	[0.46, 2.49]
CupVolume(mm3)		
Mean(SD)	0.11 (0.11)	0.10 (0.11)
Median	0.07	0.07
Min, Max	[0.00, 0.88]	[0.00, 0.81]
C/DAreaRatio		
Mean(SD)	0.26 (0.15)	0.26 (0.16)
Median	0.26	0.25
Min, Max	[0.00, 0.71]	[0.00, 0.76]
C/DHRatio		
Mean(SD)	0.52 (0.21)	0.51 (0.22)
Median	0.54	0.53
Min, Max	[0.00, 0.97]	[0.00, 0.97]
C/DVRatio		
Mean(SD)	0.46 (0.17)	0.45 (0.18)
Median	0.49	0.48
Min, Max	[0.00, 0.83]	[0.00, 0.82]

<u>Conclusions</u>

The SOLIX has the same intended use as the legally marketed predicate devices identified in this 510(k) notification. The IFU statement differs from those for the predicate devices, but these differences do not change the intended use of the device. The technological characteristics of the SOLIX differ from those of the predicate devices, however, the differences do not raise new or different questions of safety or effectiveness. Results of the non-clinical performance testing demonstrate that the SOLIX functions as intended. Results of 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 as or better than the legally marketed device predicates.