



July 25, 2019

SIS AG, Surgical Instrument Systems
% Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, CO 80127

Re: K182659
Trade/Device Name: Galilei G6 Lens Professional
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: MXK, HJO
Dated: June 24, 2019
Received: June 25, 2019

Dear Kevin Walls:

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,

for Bradley Cunningham
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)

K182659

Device Name

Galilei G6 Lens Professional

Indications for Use (Describe)

The Galilei G6 Lens Professional) is designed to take images of the anterior segment of the eye, which includes cornea, iris, pupil, anterior chamber, and crystalline lens. To evaluate:

- Corneal shape
- Pachymetry (corneal thickness)
- Position of the cornea relative to iris and lens
- Anterior and posterior opacity
- Anterior chamber angle
- Anterior chamber depth
- Volume of the anterior chamber
- White-to-white distance
- Pupil size
- Condition and position of implants (e.g. IOL, phakic IOLs, intracorneal rings)
- Location of cataracts (nuclear, sub capsular and or cortical), using cross slit imaging with densitometry
- Condition of the lens (opaque crystalline lens)
- Lens shape
- Crystalline lens thickness

The Galilei G6 Lens Professional is designed to additionally evaluate:

- Axial length

The Galilei G6 Lens Professional) also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary GALILEI Lens Professional

I. SUBMITTER

SIS AG, Surgical Instrument Systems
Allmendstrasse 11
CH-2502 Port
Switzerland
Frank Ziemer, CEO
Phone: +41 32 332 70 70
Fax: +41 32 332 70 71
Email: frank.ziemer@ziemergroup.com

Contact Person:
Mr. Kevin Walls
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127
Phone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

Date Prepared: July 24, 2019

II. DEVICE

Name of Device: Galilei G6 Lens Professional
Common or Usual Name: G6, Galilei
Classification Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: MXK, HJO
Regulation Number: 886.1850

III. PREDICATE DEVICE

The following two predicate devices were chosen:

1. Galilei G4 Dual Scheimpflug Analyzer (K051940) for topography/ tomography measurements only and
2. Pentacam® AXL (K152311) for topography/tomography as well as biometry measurements

The Galilei G6 Lens Professional is (in hardware and software) identical to the Galilei G4 Dual Scheimpflug Analyzer but includes an additional biometry module (hardware and software) referred to as an “EBR Accessory” for evaluating axial length. The Galilei G4 Dual Scheimpflug Analyzer is already cleared by the FDA (K051940) and was audited by the FDA in 2017 without deviations.

The Pentacam® AXL was chosen as a predicate device because it is the only FDA approved device on the market that has substantially similar measurement principles to the Galilei G6. Both the Galilei G6 Lens Professional and the Pentacam® AXL devices use a combination of Scheimpflug topography/tomography and axial length measurements based on partial coherence interferometry.

IV. DEVICE DESCRIPTION

The Galilei G6 Lens Professional is (in hardware and software) identical to the Galilei G4 Dual Scheimpflug Analyzer but features an additional biometry module (hardware and software) referred to as “EBR Accessory”.

The Galilei G6 Lens Professional consists of the following functional units:

- Measurement Head – Container for the cameras, light sources, monitor drivers and electronics. The Placido disk and Dual-Scheimpflug imaging is integrated into the Measurement Head, which performs a 180-degree rotation during data acquisition.
- Main Monitor - Display and navigation through the software, selection of functions.
- PC box – Container of the power supply and the computer. Periphery (Main monitor, mouse and keyboard) is connected directly to the computer.
- Elevation Table - Height-adjustable instrument table with locking wheels.
- EBR Accessory – Container of the EBR main printed circuit board as well as the optical and mechanical components such as a scanner and a partial coherence interferometer used for biometry measurements. Mounted inside the PC box.

The GALILEI G6 device takes images of the anterior segment of the eye, which includes the cornea, iris, pupil, limbus, anterior chamber and crystalline lens. Topography and anterior segment tomography are calculated from those images.

A pair of slit light images are recorded simultaneously with two cameras placed at opposite sides at an angle of 45°. Due to the Scheimpflug principle, an angled orientation of the camera’s sensor allows a sharp focus over the entire image in spite of the 45° recording angle.

The images are then analyzed and anterior cornea, posterior cornea, anterior lens and iris surfaces are detected. This information is then used to reconstruct a three-dimensional model of the anterior chamber.

Twenty (20) concentric rings in the Placido are reflected on the anterior surface of the cornea and recorded by a top-view camera in the center of the measurement head. The sizes and shapes of the recorded rings are used to calculate the curvature of the anterior surface of the eye.

Both the Placido and Scheimpflug information are then merged to a single model of the eye.

The EBR Accessory enables the Galilei G6 to take an optical A-scan by means of partial coherence interferometry.

A beam of partial coherence infrared light is directed along the optical axis into the eye. Whenever it passes a transition between layers with different refractive indices (e.g., corneal surfaces, crystalline lens surfaces, retinal surfaces), a portion of the light is reflected back towards the source. The reflected light is compared to a reference beam passing through a light path of adjustable optical length. The length of the reference arm is varied by a scanner.

When the optical lengths of sample arm and reference arm match to within the coherence length of the partial coherence light source, an interference peak is detected and the corresponding layer within the eye is deduced.

V. INDICATIONS FOR USE

The Galilei G6 Lens Professional is designed to take images of the anterior segment of the eye, which includes cornea, iris, pupil, anterior chamber, and crystalline lens. To evaluate:

- Corneal shape
- Pachymetry (corneal thickness)
- Position of the cornea relative to iris and lens
- Anterior and posterior opacity
- Anterior chamber angle
- Anterior chamber depth
- Volume of the anterior chamber
- White-to-white distance
- Pupil size
- Condition and position of implants (e.g. IOL, phakic IOLs, intracorneal rings)
- Location of cataracts (nuclear, sub capsular and or cortical), using cross slit imaging with densitometry
- Condition of the lens (opaque crystalline lens)
- Lens shape
- Crystalline lens thickness

The Galilei G6 Lens Professional is designed to additionally evaluate:

- Axial length

The Galilei G6 Lens Professional) also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The extent of equivalence to the two predicate devices (see section III) is documented in the following tables

Table 1: Comparison Table of Galilei G6 Lens Professional and Galilei G4 Dual Scheimpflug Analyzer

Characteristics	Galilei G6 Lens Professional	Galilei G4 Dual Scheimpflug Analyzer	Difference
510(k) number	K182659 (pending)	K051940	n/a
Intended use	<p>The Galilei G6 Lens Professional is designed to take images of the anterior segment of the eye, which includes cornea, iris, pupil, anterior chamber, and crystalline lens. To evaluate:</p> <ul style="list-style-type: none"> • Corneal shape • Pachymetry (corneal thickness) • Position of the cornea relative to iris and lens • Anterior and posterior opacity • Anterior chamber angle • Anterior chamber depth • Volume of the anterior chamber • White-to-white distance • Pupil size • Condition and position of implants (e.g. IOL, phakic IOLs, intracorneal rings) • Location of cataracts (nuclear, sub capsular and or cortical), using cross slit imaging with densitometry • Condition of the lens (opaque crystalline lens) • Lens shape • Crystalline lens thickness <p>The GALILEI G6 Lens Professional is designed to additionally evaluate:</p> <ul style="list-style-type: none"> • Axial length 	<p>The Galilei G4 Dual-Scheimpflug Analyzer is a device intended to take images of the anterior segment of the eye, which includes cornea, iris, pupil, anterior chamber, and lens, to evaluate and analyse:</p> <ul style="list-style-type: none"> • Corneal shape • Lens shape • Pachymetry (thickness of the cornea) • Pupil size • Lens thickness • Condition of the lens <ul style="list-style-type: none"> ○ Location of cataracts (nuclear, subcapsular and or cortical), using Scheimpflug slit imaging with densitometry ○ State of the lens (opaque crystalline lens) • Condition and position of implants (e.g. IOLs, phakic IOLs, intracorneal rings) • Anterior chamber (size, volume and angle) • Scheimpflug Image • Position of the cornea relative to iris and lens 	<p>No difference for measurements of the anterior chamber.</p> <p>The Galilei G6 Lens Professional additionally evaluates axial length. Safety and effectiveness are addressed in a clinical study with respect to the second predicate device.</p>
Measurement principle anterior segment & Topography	<p>Scheimpflug photography for cross-sectional anterior imaging of the anterior chamber.</p> <p>Scheimpflug photography and Placido ring imaging for anterior corneal surface topography</p>	<p>Scheimpflug photography for cross-sectional anterior imaging of the anterior chamber.</p> <p>Scheimpflug photography and Placido ring imaging for anterior corneal surface topography</p>	No difference

Characteristics	Galilei G6 Lens Professional	Galilei G4 Dual Scheimpflug Analyzer	Difference
Keratometry range	4.5 - 13.5 mm (25 - 75 D)	4.5 - 13.5 mm (25 - 75 D)	No difference
Imaging Technology	Digital camera	Digital camera	No difference
Scheimpflug	Source: LED Wavelength: 470 nm	Source: LED Wavelength: 470 nm	No difference
Placido	Source: LED Wavelength: 750 nm	Source: LED Wavelength: 750 nm	No difference
Device concept	Tabletop	Tabletop	No difference
Alignment	Operator guided by monitor and joystick	Operator guided by monitor and joystick	No difference
Operating Distance	58 mm	58 mm	No difference
Fixation Target	Source: LED Wavelength: 617 nm	Source: LED Wavelength: 617 nm	No difference
Power Requirement	110/220 VAC, 50/60 Hz	110/220 VAC, 50/60 Hz	No difference

Table 2: Comparison Table of Galilei G6 Lens Professional and Pentacam® AXL

Characteristics	Galilei G6 Lens Professional	Pentacam® AXL	Difference	Comment
510(k) number	K182659 (pending)	K152311	n/a	n/a
Intended use	<p>The GALILEI G6 Lens Professional is designed to take images of the anterior segment of the eye, which includes cornea, iris, pupil, anterior chamber, and crystalline lens. To evaluate:</p> <ul style="list-style-type: none"> • Corneal shape • Pachymetry (corneal thickness) • Position of the cornea relative to iris and lens • Anterior and posterior opacity • Anterior chamber angle • Anterior chamber depth • Volume of the anterior chamber • White-to-white distance • Pupil size • Condition and position of implants (e.g. IOL, phakic IOLs, intracorneal rings) • Location of cataracts (nuclear, sub capsular and or cortical), using cross slit imaging with densitometry • Condition of the lens (opaque crystalline lens) • Lens shape • Crystalline lens thickness <p>The GALILEI G6 Lens Professional is designed to additionally evaluate:</p> <ul style="list-style-type: none"> • Axial length <p>The Galilei G6 Lens Professional also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.</p>	<p>The Pentacam® AXL is designed to take photos of the anterior segment of the eye, which includes cornea, pupil, anterior chamber and lens of the eye. To evaluate:</p> <ul style="list-style-type: none"> • corneal shape, • analyze condition of the lens (opaque crystalline lens), • analyze the anterior chamber angle, • analyze anterior chamber depth, • analyze the volume of the anterior chamber, • analyze anterior or posterior cortical opacity, • analyze the location of cataracts (nuclear, sub capsular and or cortical), using cross slit imaging with densitometry • corneal thickness, • axial length, • white-to-white distance. <p>The Pentacam® AXL also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.</p>	Minor difference	<p>The Pentacam® AXL does not provide lens thickness, lens shape and pupil size.</p> <p>Lens thickness, lens shape and pupil size are not used for intraocular lens calculation. The difference doesn't alter the two intended uses that are new compared to the G4 (evaluation of axial length, determining the power of the intraocular lens for implantation) and is therefore not expected to affect safety and effectiveness.</p>

Characteristics	Galilei G6 Lens Professional	Pentacam® AXL	Difference	Comment
Anterior Chamber				
Measurement principle anterior segment & Topography	<p>Scheimpflug photography for cross-sectional anterior imaging of the anterior chamber.</p> <p>Scheimpflug photography and Placido ring imaging for anterior corneal surface topography</p>	<p>Scheimpflug photography for cross-sectional anterior imaging of the anterior chamber</p> <p>Scheimpflug photography for anterior corneal surface topography</p>	Minor difference	<p>The Pentacam® AXL does not feature Placido ring imaging for conducting topography. Anterior corneal surface topography may be assessed with either technology.</p> <p>Safety and effectiveness are addressed in a clinical study with respect to the second predicate device.</p>
Keratometry range	4.5 - 13.5 mm (25 - 75 D)	3 - 38 mm (9 - 99 D)	Minor difference	<p>Keratometry range of both devices is sufficiently large to cover any corneal shape in any human subject.</p> <p>The difference is therefore not expected to affect safety and effectiveness.</p>
Imaging Technology	Digital camera	Digital camera	No difference	n/a
Scheimpflug	Source: LED Wavelength: 470 nm	Source: LED Wavelength: 475 nm	No difference	n/a
Placido	Source: LED Wavelength: 750 nm	n/a	Minor difference	<p>The Pentacam® AXL does not feature Placido ring imaging for conducting topography.</p> <p>Safety with respect to eye safety is guaranteed by compliance with the respective standards, notably IEC 60825-1.</p>

Characteristics	Galilei G6 Lens Professional	Pentacam® AXL	Difference	Comment
Biometry				
Measurement principle axial biometry	Partial coherence interferometry	Partial coherence interferometry	No difference	n/a
Biometry	Source: SLED Wavelength: 880 nm Laser class: 1 Laser class embedded: 3B	Source: SLED Wavelength: 880 nm Laser class: 1 Laser class embedded: 3B	No difference	n/a
Axial length range	14 - 40 mm	14 - 40 mm	No difference	n/a
Device				
Device concept	Tabletop	Tabletop	No difference	n/a
Alignment	Operator guided by monitor and joystick	Operator guided by monitor and joystick	No difference	n/a
Operating Distance	58 mm	80 mm	Minor difference	Exact focusing distance depends on the respective imaging optics. Both 58mm and 80mm represent safe distances in terms of not accidentally touching the eye. The difference is therefore not expected to affect safety and effectiveness.
Fixation Target	Source: LED Wavelength: 617 nm	Source: SLED Wavelength: 880 nm	Minor difference	Both wavelengths are suitable for fixation as they are visible to the human eye under direct fixation. The difference is therefore not expected to affect safety and effectiveness.

Characteristics	Galilei G6 Lens Professional	Pentacam® AXL	Difference	Comment
Power Requirement	110/220 VAC, 50/60 Hz	110/220 VAC, 50/60 Hz	No difference	n/a

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical testing

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Galilei G6 Lens Professional. The device complies with the IEC 60601-1 and IEC 60825-1 standards for safety and 60IEC 60601-2 standard for EMC.

Bench performance testing

Bench performance tests demonstrating accuracy and precision of the measured parameters of the eye were performed with our device.

Software Verification and Validation testing

As recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Software verification and validation was performed to confirm that the software performs as intended and the corresponding documentation was provided. The software for this device is rated as "major" level of concern, as inaccurately measured or displayed ocular parameters may mislead the physician in the clinical assessment. The device complies with the IEC 62304 for Medical Device Software life-cycle processes.

Clinical Studies

Comparison Galilei G6 Lens Professional with Pentacam® AXL

Study description:

A clinical study was conducted to support the substantial equivalence of the Galilei G6 Lens Professional to the predicate device, the Pentacam® AXL. Since the Galilei G4 Dual Scheimpflug Analyzer and Galilei G6 Lens Professional are identical except that the Galilei G6 Lens Professional has an additional EBR Module for measuring axial length, only the Galilei G6 Lens Professional and the Pentacam® AXL were included in the study. The primary objectives of this clinical study were to:

1. evaluate the inter-device repeatability, inter-operator repeatability and reproducibility of the GALILEI G6 Lens Professional in repeated measurements of anterior segment geometry and axial intraocular distances and,
2. demonstrate substantial equivalence through examining agreement of the GALILEI G6 Lens Professional measurements to those of the Pentacam® AXL.

Study design:

The clinical study was a prospective, observational, one-center study. Of the total 117 enrolled and measured subjects, 12 subjects were discontinued from the study because they required repeat measurements that would have exceeded the recommended maximum number of daily measurements for patient safety and per protocol. Reasons for discontinuation included dense cataract, inability to hold gaze, see the fixation target or keep the eye open during the measurement, and excessive head or eye movements, all of which prevented extensive data collection with PAXL and Galilei G6.

The mean age of the subjects involved in this study was 40.7 ± 16.3 years. A total of 105 eyes of 105 subjects were assessed, 49 being right eyes and 56 being left eyes. Only one eye of each subject

was measured, and 20 eyes each were measured to represent each of the following five eye populations:

- 1) normal eyes (phakic eyes without cataracts or corneal disease),
- 2) eyes with varying degrees of cataract,
- 3) eyes with high myopia,
- 4) eyes with high hyperopia,
- 5) eyes with post-keratorefractive surgery condition.

Additional 5 analyzed eyes consisted of 2 eyes with severe keratoconus and 3 eyes with prior cross-linking treatment. Of the 105 assessed subjects, 63 were males and 42 were females. Ethnicity was composed of 100 Non-Hispanics and 5 Hispanics. Race consisted of 98 Whites, 5 Asians, and 2 American/Alaskan Natives. The 20 patients with cataract who completed all measurements included not only eyes with moderate cataract, but also eyes with severe cataract with grades as high as 4 in the Lens Opacification Classification System (LOCS) III, in order to ensure that cataracts of various severity grades, particularly of severe cataract, can be accurately and precisely assessed with the Galilei G6. In the LOCS III, cataract severity ranges from grade 1 (very early stage) to grade 5 (severe).

Results:

- In terms of agreement, the Galilei G6 demonstrates substantially equivalent performance to the predicate device, except for WtW.
- WtW is known to be different between state-of-the-art devices, and device specific offsets are commonly used in clinical practice to account for inter-device differences. Inter-device differences between the state-of-the-art devices and Galilei G6 are substantially equivalent to those between state-of-the-art devices and the PAXL.
- Repeatability and reproducibility attained with the Galilei G6 are substantially equivalent to those attained with the PAXL.
- Minor technological differences between the Galilei G6 and the Pentacam AXL raise no new issues of safety or effectiveness.
- No adverse effects and complications were observed or are to be expected.

Summary:

Performance data demonstrates that the Galilei G6 Lens Professional is as safe and effective as the predicate device, the Pentacam® AXL. Minor technological differences between the Galilei G6 and the predicate device raise no new issues of safety or effectiveness. No adverse effects or complications were observed or are to be expected.

In-house Precision Testing: Results

An internal clinical study was conducted

- 1) to evaluate precision in terms of repeatability (intra-device, intra-operator) and reproducibility (inter-device, inter-operator) of the GALILEI G6 Lens Professional for repeated measurements and
- 2) to compare the precision of the Galilei G6 Lens Professional to the reported values of the Pentacam® AXL for normal eyes.

Anterior segment geometry and axial intraocular distances under assessment included:

1. AL
2. CCT
3. R flat
4. R steep
5. Rm
6. CC
7. A flat
8. ACD
9. WtW

Repeatability in this study was defined as the variation in measurements within the Galilei G6 across 3 repeated measurements for a given device and operator. The values in **Table 3** illustrate that expected differences when taking another measurement by the same operator using the same device are less than 1%, except for *CC* (8.79%) and *A flat* (3.79%), which indicates high repeatability for most parameters.

Repeatability CV values are generally comparable to those with the PAXL (**Table 4**). Small differences where the repeatability CV with the PAXL is smaller than that with the Galilei G6 are clinically irrelevant, because they translate to refractive differences below 0.17D (=1/6 of a diopter = optical infinity = vergence from a distance of 6 meters that is perceived as coming from infinity), i.e. below the minimum defocus that is discernible to the human eye. In consideration of Gullstrand's #1 schematic eye [1], having an anterior corneal radius of curvature of 7.7mm and a corneal refractive index of 1.376, a difference of 0.01mm, for example, in anterior curvature corresponds to a difference in anterior corneal power of less than 0.07 diopters. The repeatability SD value of 0.11D for *CC* corresponds to the repeatability SD values reported in literature studies with Pentacam HR and other corneal topographers and keratometers on the market.

Table 3: Repeatability and reproducibility with the Galilei G6 in normal eyes (all three Galilei devices combined)

Measure	Number of subjects	Mean	Repeatability		Reproducibility	
			SD	CV [%]	SD	CV [%]
<i>AL</i> [mm]	12	23.91	0.02	0.08	0.02	0.08
<i>CCT</i> [um]	12	578	4.50	0.78	6.79	1.17
<i>R flat</i> [mm]	12	7.84	0.02	0.21	0.02	0.28
<i>R steep</i> [mm]	12	7.62	0.02	0.21	0.02	0.27
<i>Rm</i> [mm]	12	7.72	0.01	0.16	0.02	0.24
<i>CC</i> [D]	12	1.27	0.11	8.79	0.11	8.98
<i>A flat</i> [deg]	12	90	3.40	3.79	3.44	3.85
<i>ACD</i> [mm]	12	3.54	0.03	0.85	0.03	0.86
<i>WtW</i> [mm]	12	12.26	0.03	0.21	0.03	0.24

Table 4: Repeatability and reproducibility with the PAXL in normal eyes, as reported in K152311

Measure	Number of subjects	Mean	Repeatability		Reproducibility	
			SD	CV [%]	SD	CV [%]
<i>AL</i> [mm]	40	23.78	0.03	0.10	0.03	0.13
<i>CCT</i> [um]	40	550	4.00	0.67	5.00	0.90
<i>R flat</i> [mm]	40	7.85	0.02	0.15	0.017	0.21
<i>R steep</i> [mm]	40	7.69	0.02	0.15	0.018	0.23
<i>Rm</i> [mm]	40	7.77	0.01	0.13	0.015	0.19
<i>CC</i> [D]	40	0.92	0.07	7.68	0.10	10.84
<i>A flat</i> [deg]	40	102	4.90	4.76	6.35	6.22
<i>ACD</i> [mm]	40	3.53	0.02	0.61	0.026	0.75
<i>WtW</i> [mm]	40	11.8	0.04	0.37	0.08	0.70

Under the assumption of the same study design with the PAXL (3 devices, 3 operators, 3 measurements) repeatability CV values with the Galilei G6 as assessed with three different operators using three Galilei devices in normal eyes are consistent with those reported with the PAXL.

VIII. CONCLUSIONS

The Galilei G6 Lens Professional, being identical to the first predicate device in all common functions, the Galilei G4 Dual Scheimpflug Analyzer, was found to be substantially equivalent to the second predicate device, the Pentacam® AXL. The non-clinical data support the safety of the device, and the hardware and software verification and validation demonstrate that the Galilei G6 Lens Professional should perform as intended in the specified use conditions. The clinical data demonstrate that the Galilei G6 Lens Professional performs substantially equivalently to the predicate devices that are currently marketed for the same intended use.