



Carl Zeiss Meditec AG
% Lisa Graney
Consultant
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K173771
Trade/Device Name: IOLMaster 700
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 11, 2017
Received: July 18, 2018

Dear Lisa Graney:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alexander Beylin -S

2018.08.24 14:15:53 -04'00'

for Malvina Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose,
and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173771

Device Name

IOLMaster 700

Indications for Use (Describe)

The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures:

- Lens thickness
- Corneal curvature and thickness
- Axial length
- Anterior chamber depth
- Pupil diameter
- White-to-white distance (WTW)

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)

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510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the IOLMaster 700 is provided below:

1. SUBMITTER:

Applicant: Carl Zeiss Meditec AG
Goeschwizer Strasse 51-52
D-07745 Jena
Germany

Contact: Lisa Graney
Consultant
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Date Prepared: July 18, 2018

2. DEVICE:

Device Trade Name: IOLMaster 700
Device Common Name: Biometer
Classification Name: 21 CFR 886.1850, AC-powered slit lamp
biomicroscope
Regulatory Class: Class II
Product Code: HJO

3. PREDICATE DEVICE:

The predicate device is the previous version of the IOLMaster 700, cleared under K170171.

4. DEVICE DESCRIPTION:

The IOLMaster 700 is a non-invasive optical biometry instrument for visualization and measurement of ocular structures. The IOLMaster 700 is the latest generation device in the

IOLMaster series. The version of the IOLMaster 700 that is the subject of this submission is a modified version of the IOLMaster 700 cleared under K170171.

5. INDICATIONS FOR USE:

“The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures:

- Lens thickness
- Corneal curvature and thickness
- Axial length
- Anterior chamber depth
- Pupil diameter
- White-to-white distance (WTW)

6. TECHNOLOGICAL COMPARISON:

DEVICE CHARACTERISTICS	PROPOSED IOLMASTER 700 (CARL ZEISS MEDITEC AG)	PREDICATE IOLMASTER 700 (CARL ZEISS MEDITEC AG) K170171
Principles of Operation	Spectral domain interferometry (OCT principle), Light spot projection (infrared LEDs), Image capturing	Identical
Feature - Corneal Curvature Measurement:		
<i>Keratometry (considering anterior corneal surface)</i>	Available	Available
Technology for obtaining measurements/images	Telecentric keratometry = distance independent, Light spot projection (infrared LEDs)	Identical
Measurement range / Resolution of display	5 mm to 11 mm / 0.01 mm	Identical
<i>Total Keratometry (considering anterior and posterior corneal surface) calculated by SW algorithm</i>	Available (with additional algorithm)	Not available

Total Keratometry measurement values:		
Spherical Equivalent (TSE) [D]	Available	Not available
Corneal cylinder (TΔD) [D]	Available	Not available
Axis (Tα) [°]	Available	Not available
Posterior corneal surface measurement values:		
Spherical Equivalent (PSE) [D]	Available	Not available
Corneal cylinder (PΔD) [D]	Available	Not available
Axis (Pα) [°]	Available	Not available
Feature - Lens Thickness Measurement (LT):		
Technology for obtaining measurements/images	Swept source laser, Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical
Measurement range / Resolution of display	Phakic eye range 1.0 mm to 10 mm / 0.01 mm Pseudophakic eye range 0.13 mm to 2.5 mm / 0.01mm	Identical
Feature - Central Corneal Thickness Measurement (CCT):		
Technology for obtaining measurement	Swept source laser, Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical
Measurement range / Resolution of display	0.2 mm to 1.2 mm / 1 μm	Identical
Feature - Anterior Chamber Depth Measurement (ACD):		
Technology for obtaining measurement	Swept source laser, Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical
Measurement range / Resolution of display	0.7 mm to 8 mm / 0.01 mm	Identical
Feature - Axial Length Measurement (AL):		
Technology for obtaining measurement	Swept source laser, Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical

Measurement range / Resolution of display	14 mm to 38 mm / 0.01 mm	Identical
Feature - Pupil Diameter Measurement (P):		
Technology for obtaining measurement	Image capturing of the iris with internal digital camera.	Identical
Measurement range / Resolution of display	1 mm to 12 mm / 0.1 mm	Identical
Feature - White-to-White Measurement (WTW):		
Technology for obtaining measurement	Image capturing of the iris with internal digital camera.	Identical
Measurement range / Resolution of display	8 mm to 16 mm / 0.1 mm	Identical
Feature - Reference Image Functionality:		
Technology for obtaining measurement	Green LEDs for green light illumination for image capturing of scleral vessels with internal digital camera.	Identical
Feature - Computational formulas	Haigis Suite (includes Haigis, Haigis-L and Haigis-T); Hoffer Q; Holladay 2; SRK [®] /T; Barrett Suite (includes Barrett Universal II, Barrett Toric and Barrett True K); Holladay 1	Haigis Suite (includes Haigis, Haigis-L and Haigis-T); Hoffer Q; Holladay 2; SRK [®] /T
Optical radiation:		
Illumination for OCT	Light source: Tunable laser Wavelength range: 1035 nm to 1080 nm Maximum power output: 1.67 mW Max. exposure time per eye and day: 8 h	Identical
Illumination for keratometer (corneal curvature) measurement	Light source: LED Wavelength: 950 nm Delivered power: < 500 μ W	Identical
Illumination for WTW measurement	Light source: LED Wavelength: 860 nm/880 nm Delivered power: < 500 μ W	Identical
Green illumination for sclera images	Source: LED Wavelength: 520 nm Delivered power: < 100 μ W Max. exposure time per eye and day: 27 min (corresponding to approx. 3000 measurements)	Identical
Fixation light	Source: LED Wavelength: 660 nm Delivered power: < 1 μ W	Identical

Electrical Data:		
Rated voltage / frequency	100 V to 240 V AC ($\pm 10\%$) / 50/60 Hz	Identical
Power consumption: Basic unit In standby mode	150 W 1 W	Identical
Electrical Safety Parameters:		
Protection class	I	Identical
Protection mode	IP 20	Identical
Device type	B (IEC 60601-1)	Identical
Laser class	Class 1 (IEC 60825-1:2007) In device (not accessible): 3B	Identical
Ambient conditions:		
for intended use	Temperature: 10°C to +35°C, Relative humidity: 30% to 80% (noncondensing)	Identical
for storage and transport	Temperature: -20°C to +60°C, Relative humidity: 10% to 90% (noncondensing)	Identical

7. PERFORMANCE DATA:

7.1. Biocompatibility Testing:

The device materials are identical to the predicate device. Therefore, patient contact information is not needed for this device.

7.2. Electromagnetic Compatibility, Electrical, Thermal, Mechanical, Laser and Optical Radiation Safety Testing:

No hardware changes have been made from the predicate IOLMaster 700 (K170171); therefore, no EMC, electrical, thermal, mechanical, laser, or optical radiation safety testing is provided in this submission.

7.3. Software Verification and Validation Testing:

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of

Premarket Submissions for Software Contained in Medical Devices.” Verification and validation of the IOLMaster 700 was conducted to ensure that the product works as designed.

7.4. Bench Testing:

To verify the accuracy and repeatability of the IOLMaster 700 when making posterior corneal surface (PCS) and Total Keratometry (TK) measurements, bench testing was conducted in which the device acquired images of test targets of known curvatures. The results are then compared to the expected values and differences from the expected values must be within the tolerance range identified. This testing showed that the modified IOLMaster 700 is able to acquire posterior corneal surface (PCS) and Total Keratometry (TK) measurements which are accurate and repeatable.

7.5. Animal Testing:

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

7.6. Clinical Data:

Clinical studies were conducted to obtain raw image data of normal eyes¹ (cataract and non-cataract) as well as post LVC eyes. The image data were analyzed using the Total Keratometry (TK) / posterior corneal surface (PCS) measurement algorithm in the modified IOLMaster 700 (subject device) and compared to conventional keratometry in the predicate device IOLMaster 700.

The objectives of this testing were as follows:

- To characterize the relationship between TK and conventional keratometry measurements.
- To characterize the relationships between PCS measurements and the respective Gullstrand model eye-derived assumptions.
- To characterize the repeatability and reproducibility of TK and PCS measurements.

7.6.1. Normal eyes (Cataract and non-cataract eyes)

a) Clinical study IOLM71

The following raw data was used for testing the stated objectives:

- Raw data collected within a prospective, non-significant risk clinical study conducted at three sites.
- Collection of the data using the same measurement and image acquisition method as the current IOLMaster 700.
- Eyes with low to high cylinder were enrolled in the study.

¹ Normal eyes = without prior Laser Vision Correction

- Included datasets consisted of 142 normal eyes (i.e. without previous surgery or any known pathologies except for cataract) and 738 measurements in the normal (i.e. without previous surgery or any known pathologies except for cataract).

b) Clinical study IOLMaster 2017-01909

The following data were used for repeatability and reproducibility analysis:

- Prospective, monocentric, non-significant risk clinical R&R study.
- Collection of the data at study site employed three IOLMaster 700 devices.
- Included datasets consisted of 32 non-cataract eyes and 281 measurements as well as 31 cataract eyes and 278 measurements. Only one eye of each patient was included.

Results

a) Clinical study IOLM71

For each of the normal eye PCS measurements and TK values (spherical equivalent, cylinder, axis) were compared to conventional keratometry and Gullstrand model derived posterior corneal surfaces.

Additionally, to address variability, Bland-Altman testing was conducted to assess the agreement of:

- the spherical equivalents of TK and keratometry in normal eyes,
- the cylinders of TK and keratometry in normal eyes,
- the cylinders of TK and keratometry in normal eyes with with-the-rule (WTR) and against-the-rule (ATR) astigmatism,
- the axis with $\Delta D \geq 0.75$ D of TK and keratometry in normal eyes,
- the spherical equivalents of PCS and keratometry-Gullstrand ratio-derived PCS in normal eyes
- the cylinders of PCS and keratometry-Gullstrand ratio-derived PCS in normal eyes
- the axis with $PAD \geq 0.1$ D of PCS and keratometry in normal eyes.

Results are summarized in [Table 1](#).

Abbreviations used in [Table 1](#):

SE	Spherical equivalent of corneal power according to keratometry [D]
ΔD	Cylinder of corneal power according to keratometry [D]
α	Axis of the steep meridian according to keratometry [°]
TSE	Spherical equivalent of corneal power according to TK [D]
T ΔD	Corneal cylinder of corneal power according to TK [D]
T α	Axis of the steep meridian according to TK [°]
PSE	Spherical equivalent of posterior corneal power [D]
P ΔD	Cylinder of posterior corneal power [D]

$P\alpha$ Axis of the steep meridian of posterior corneal power [$^{\circ}$]

WTR With-the-rule astigmatism, where the steep meridian is roughly vertical.

ATR Against-the-rule astigmatism, where the steep meridian is roughly horizontal.

Table 1: Mean Difference Summary Statistics

Parameter	N	Difference							
		Mean	SD	Min	Med	Max	95% CI for Mean	p-value	95% LOA
Keratometry									
PSE vs. PSE _{Kera} [D]	141	0.027	0.114	-0.301	0.031	0.414	0.019, 0.036	< 0.001	0.255, -0.200
PAD vs. PAD _{Kera} [D]	129	-0.150	0.132	-0.511	-0.158	0.225	-0.160, -0.140	< 0.001	0.114, -0.414
Pα vs. α [°] PAD ≥ 0.1 D	117	-3.409	31.152	-88.187	-2.326	87.786	-5.879, -0.939	0.007	58.896, -65.713
TSE vs. SE [D]	141	0.013	0.110	-0.303	0.016	0.383	0.005, 0.022	0.002	0.233, -0.206
TAD vs. AD [D]	129	-0.032	0.183	-0.444	-0.038	0.441	-0.046, -0.018	< 0.001	0.334, -0.398
WTR	76	-0.147	0.110	-0.444	-0.155	0.138	-0.158, -0.136	< 0.001	0.074, -0.367
ATR	33	0.185	0.120	-0.081	0.193	0.441	0.167, 0.204	< 0.001	0.424, -0.054
Tα vs. α [°] AD ≥ 0.75 D	84	0.603	3.416	-14.828	0.579	10.725	0.278, 0.927	< 0.001	7.434, -6.228

b) Clinical study IOLMaster 2017-01909

Repeatability standard deviation (SD) was estimated by the square-root of the estimated variance due to measurement error based on the random effect ANOVA model. The repeatability limit (or repeatability) was estimated with a 95% confidence limit of the difference between two repeated measurements. The reproducibility SD was estimated by the square-root of sum of the variances due to device/operator configuration, interaction between subject, and measurement error. Additionally, the coefficient of variation in percentage (CV) for repeatability were provided.

Results are summarized in [Table 2](#).

Table 2: Repeatability and Reproducibility, normal patients (n = 32 non-cataract subjects and n = 31 cataract subjects), IOLMaster 700 version 1.70 / Repeatability Analysis Population

	N Scans	Mean	Repeatability			Reproducibility		
			SD	Limit	CV%	SD	Limit	CV%
Non-cataract Subjects								
SE_TK [D]	281	43.59	0.090	0.251	0.21%	0.093	0.261	0.21%
CYL_TK [D]	281	-1.38	0.159	0.446	11.55%	0.173	0.485	12.55%
A_TK [°] (CYL_K ≥ 0.75D)	219	136.46	2.998	8.393	2.20%	3.393	9.499	2.49%
SE_PCS [D]	281	-5.88	0.030	0.085	0.52%	0.033	0.091	0.55%
CYL_PCS [D]	281	-0.36	0.047	0.132	13.06%	0.052	0.145	14.31%
A_PCS [°]	281	139.19	4.319	12.093	3.10%	5.424	15.188	3.90%
Cataract Subjects								
SE_TK [D]	278	44.16	0.088	0.246	0.20%	0.103	0.288	0.23%
CYL_TK [D]	278	-1.01	0.148	0.416	14.69%	0.159	0.446	15.77%
A_TK [°] (CYL_K ≥ 0.75D)	171	133.79	3.459	9.685	2.59%	3.854	10.791	2.88%
SE_PCS [D]	278	-5.92	0.029	0.080	0.48%	0.035	0.097	0.58%
CYL_PCS [D]	278	-0.27	0.048	0.133	17.43%	0.048	0.136	17.75%
A_PCS [°]	278	145.12	7.371	20.640	5.08%	8.949	25.058	6.17%

(SE_TK, CYL_TK, A_TK) = Spherical equivalent, Cylinder, Axis IOLMaster 700 v1.70 Total Keratometry,

(SE_PCS, CYL_PCS, A_PCS) = Spherical equivalent, Cylinder, Axis IOLMaster 700 v1.70 Posterior Corneal Surface
Reproducibility Limit = 2.8*SD.

Note: poststratification of IOLMaster 700 v 1.70 axis (A_TK) is based on the per-patient median of the IOLMaster v1.50 Cylinder (CYL_K) measurement, cut at 0.75D.

7.6.2. Post-LVC eyes

a) *Clinical study HamburgLVC*

For the quantitative comparison analyses, the data from the “HamburgLVC” study were examined

- Raw data collected within a prospective, single-site clinical study.
- Collection of the data using the same measurement and image acquisition method as the current IOLMaster 700.
- Eyes with low to high cylinder were enrolled in the study.
Included datasets consists of 30 eyes and 60 measurements (one pre- and one postoperative measurement for each eye). From the 30 eyes, 29 eyes have undergone a myopic and one eye has undergone a hyperopic LASIK treatment. Only one eye of each patient was included.

b) *Clinical study IOLMaster 2017-01909*

The following data are used for repeatability and reproducibility analysis:

- Prospective, monocentric, non-significant risk clinical R&R study.
- Collection of the data at study site employed three IOLMaster 700 devices.
- Included datasets consisted of 30 post-LVC eyes and 267 measurements. Only one eye of each patient was included.

Results

In post-LVC eyes, IOL calculation typically consists of two steps: correcting keratometry K values and using a standard formula. When the required historic data is available, the clinical history method is considered the gold standard for correcting K values. Otherwise, a history-free approximation, like Haigis-L, is typically used in clinical practice.

The dataset HamburgLVC includes post-LVC measurements and pre-LVC and post-LVC refraction data. This allows comparison of TK measurements to K values modified according to the clinical history method. As a benchmark, comparison of Haigis-L modified K values to the clinical history method was also conducted. The analysis was performed for non-toric lenses as well as for toric lenses.

Abbreviations in [Figure 1](#) and [Figure 2](#):

SE Spherical equivalent of keratometry [D]

TSE Spherical Equivalent for TK [D]

CHM Clinical History Method

CSE Spherical equivalent of postoperative corneal power derived from CHM

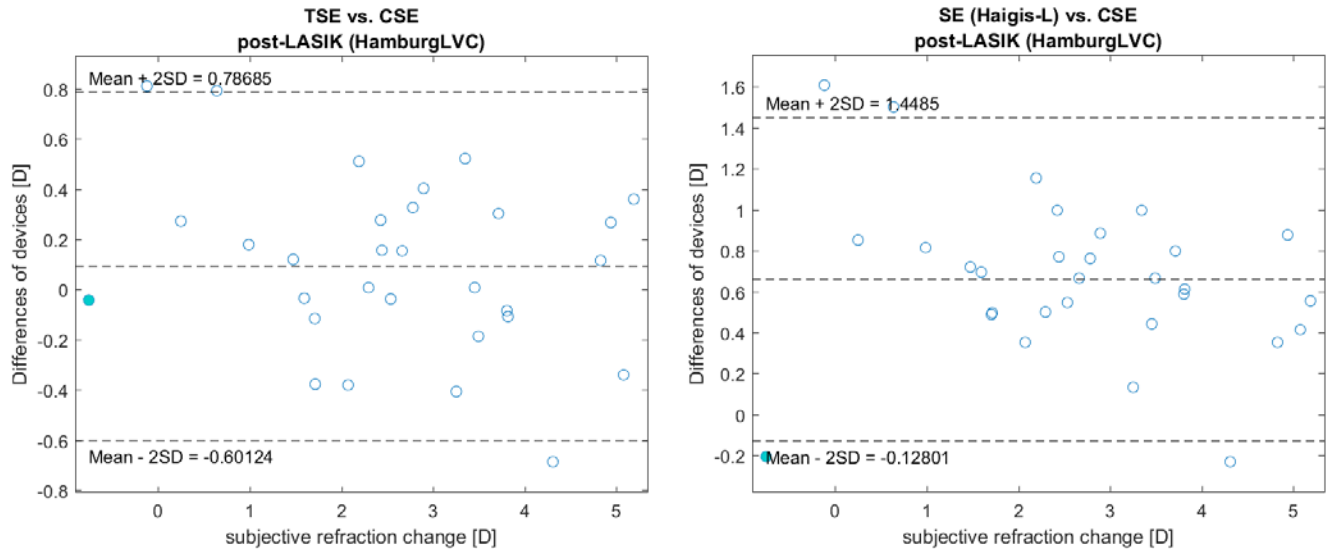


Figure 1: Distribution of disagreement of the spherical equivalents of TK and CHM (left), and of Haigis-L and CHM (right) by subjective refraction change in case of post LASIK eyes. The teal dot marks the hyperopic post-LVC measurement.

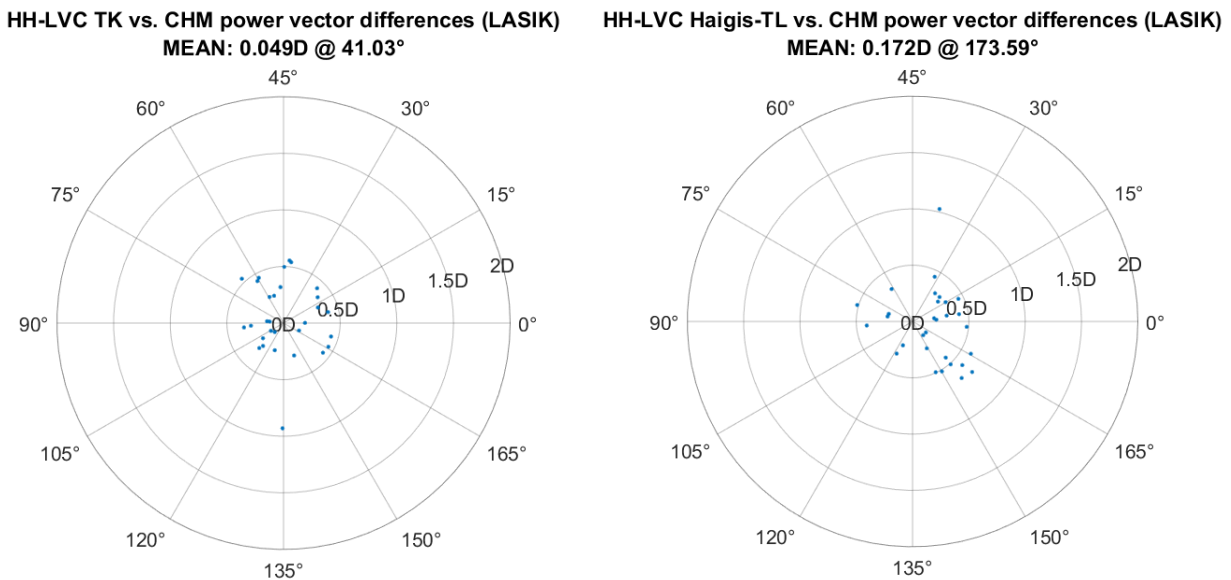


Figure 2: Double-angle plots of vector differences between corneal cylinder of TK and toric CHM (left), and as a baseline of Haigis-T corrected keratometry and toric CHM (right), respectively. The mean vector differences are 0.049 D @ 41.03° (left) and 0.172 D @ 173.59° (right).

c) *Clinical study IOLMaster 2017-01909*

Repeatability standard deviation (SD) was estimated by the square-root of the estimated variance due to measurement error based on the random effect ANOVA model. The repeatability limit (or repeatability) was estimated by the 95 % confidence limit of the difference between two repeated measurements. The reproducibility SD was estimated by the square-root of sum of the variances due to device/operator configuration, interaction between subject, and measurement error. Additionally, the coefficient of variation in percentage (CV) for repeatability were provided.

Results are summarized in [Table 3](#).

Table 3: Repeatability and Reproducibility, post LVC patients (n = 30), IOLMaster 700 version 1.70 / Repeatability Analysis Population

	N Scans	Mean	Repeatability			Reproducibility		
			SD	Limit	CV%	SD	Limit	CV%
SE_TK [D]	267	40.64	0.083	0.233	0.21	0.092	0.257	0.23
CYL_TK [D]	267	-0.91	0.135	0.379	14.82	0.148	0.414	16.19
A_TK [°] (CYL_K ≥ 0.75D)	231	150.85	5.416	15.165	3.59	5.510	15.428	3.65
SE_PCS [D]	267	-5.91	0.027	0.076	0.46	0.034	0.094	0.57
CYL_PCS [D]	267	-0.31	0.044	0.124	14.45	0.048	0.135	15.77
A_PCS [°]	267	153.01	11.236	31.462	7.34	11.345	31.767	7.41

(SE_TK, CYL_TK, A_TK) = Spherical equivalent, Cylinder, Axis IOLMaster 700 v1.70 Total Keratometry,
(SE_PCS, CYL_PCS, A_PCS) = Spherical equivalent, Cylinder, Axis IOLMaster 700 v1.70 Posterior Corneal Surface

Reproducibility Limit = 2.8*SD.

Note: poststratification of IOLMaster 700 v 1.70 axis (A_TK) is based on the per-patient median of the IOLMaster v1.50 Cylinder (CYL_K) measurement, cut at 0.75D.

7.6.3. Conclusion

Normal eyes

The analysis of the data shows that the spherical equivalent of Total Keratometry (TK) and of the conventional keratometry are interchangeable for normal eyes - non-cataract and cataract eyes - based on analysis of the mean difference and limits of agreement.

Hence, TK analysis in the modified IOLMaster 700 can be used for IOL power calculation of non-toric IOLs in normal (spherical) eyes as an alternative to conventional keratometry in the predicate IOLMaster 700.

The verification shows that TK astigmatism measurements systematically differ from keratometry as expected and in agreement with scientific literature. The results show that TK overcomes the systematic weakness of keratometry in accounting for the contribution of the posterior cornea surface to the corneal astigmatism.

Combined with the interchangeability in spherical equivalent, TK is thus suitable for IOL power calculation of toric IOLs using existing keratometry-based formulas, but not for formulas including a model of the posterior corneal astigmatism that differs from the keratometer model as a workaround of the weakness of keratometry.

The repeatability and reproducibility of TK and PCS is comparable to conventional keratometry.

Post-LVC eyes

The analysis for post-LVC eyes shows that TK measurements systematically differ from keratometry measurements in this patient group as expected. Analysis also shows that TK overcomes the systematic weakness of keratometry in accounting for changes in the back-ratio due to LVC treatment.

Individual differences between TK and the clinical history method (CHM), which is considered the established gold standard, are above the noise level and above the limit of clinical significance. However, analysis of the relative performance of the Haigis-L formula, which is an established history-free alternative to CHM, showed that TK yields results much closer to CHM results than the Haigis-L results are to CHM results.

Combined with the interchangeability in spherical equivalent in normal eyes, TK combined with a regular IOL calculation formula (e.g. Haigis) is a valid tool for IOL calculation in post-LVC eyes, particularly in cases after myopic LASIK without availability of the historic data required for CHM.

Therefore, TK analysis in the modified IOLMaster 700 can be used for IOL power calculation of both toric and non-toric IOLs in post-LVC eyes as an alternative to conventional keratometry in the predicate IOLMaster 700.

It is further concluded that the repeatability and reproducibility of TK and PCS is comparable to the that of conventional keratometry.

8. CONCLUSION:

All testing deemed necessary was conducted on the modified IOLMaster 700 to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate device.

The differences in technological characteristics do not raise different questions of safety and effectiveness and the results of performance testing demonstrate that the subject device performs in accordance with specifications and meets user needs and intended uses.

Clinical data demonstrated that TK can be used as an alternative to conventional keratometry for IOL power calculation in both normal eyes and post LASIK Vision Correction eyes for both spherical and astigmatic eyes.

Based on the detailed comparison of specifications for each of the modifications to the previously cleared IOLMaster 700, the results of performance testing and clinical testing the modified IOLMaster 700 is substantially equivalent to the predicate device IOLMaster 700, as cleared in K170171.