December 18, 2025

Tomey Corporation
℅ Roger Albright
Associate Director, Regulatory Programs
Ora LLC
138 Haverhill Street, Suite 102
Andover, Massachusetts 01810

Re: K252348
Trade/Device Name: Tomey Optical Biometer OA-2000 (OA-2000)
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: November 17, 2025
Received: November 18, 2025

Dear Roger Albright:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252348

Device Name
Tomey Optical Biometer OA-2000 (OA-2000)

Indications for Use *(Describe)*
The OA-2000 is a non-invasive, non-contact biometer intended for obtaining ocular measurements to assist in the determination of the appropriate power of an intraocular lens for implantation. The OA-2000 measures: Axial length, corneal thickness, anterior chamber depth and lens thickness.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of the 510(k) premarket notification for the Tomey OA-2000 Biometer is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

Submitter Information: (21.CFR 807.92(a)(1)

Owner/Company name, address

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Date Prepared

November 14, 2025

1. Device Name (21.CFR 807.92(a)(2)

Trade Name:	Tomey OA-2000 Biometer (OA-2000)
Common Name:	device, analysis, anterior segment
Classification Name:	Biomicroscope, Slit-Lamp, Ac-Powered
Product Code:	MXK
Subsequent Product Code :	HJO
Classification Regulation:	21 CFR 886.1850

2. Legally Marketed Predicate Device (21.CFR 807.92(a)(3)

The OA-2000 is substantially equivalent to the following legally marketed device:

510(k) Number	Trade name	Product code
K082891	LenStar LS900	HJO

3. Device Description Summary (21.CFR 807.92(a)(4)

The Tomey OA-2000 ophthalmic optical coherence biometer is an ophthalmology device used to measure the length of living tissue utilizing light interference technology and to measure the corneal shape on captured images. This device is designed to measure axial length, anterior chamber depth, corneal thickness, crystalline lens thickness, and corneal shape.

The instrument contains an internal database and has various IOL power formulae applicable to ordinary cataract surgery and/or cataract surgery of eyes with corrected corneal refractive power and provides data necessary to assist the physician in determining IOL power.

The OA-2000 biometer is equipped with a 10.4-inch large touch-screen monitor for ease of use and includes Auto Alignment and Auto Shot functions. Manual measurement is also available in the event that automatic measurement is difficult.

Fourier-domain optical biometry is a high-resolution, non-invasive optical measurement technique based on the principle of low-coherence interference. It is used to determine the distance or depth of reflective structures. Fourier-domain optical biometry is based on the principle of low-coherence interferometry. A low-coherence light source is split into two beams: one directed toward a reference mirror, and the other toward the patient's eye. Light reflected from both the reference and sample arms is combined to produce an interference pattern, but only if the optical path lengths of the two arms are closely matched. This interference signal indicates the location of reflective structures in the sample and is used to reconstruct depth-resolved images or measurements.

4. Intended Use/Indications for Use (21.CFR 807.92(a)(5)

The OA-2000 is a non-invasive, non-contact biometer intended for obtaining ocular measurements to assist in the determination of the appropriate power of an intraocular lens for implantation. The OA-2000 measures: Axial length, corneal thickness, anterior chamber depth and lens thickness.

5. Indications for Use Comparison (21.CFR 807.92(a)(5)

The OA-2000 has the same indications for use as the predicate LENSTAR LS900. Some comparable functions for use are not stated in the OA-2000 IFU as they are 510(k) exempt.

6. Technological Comparison (21.CFR 807.92(a)(6)

The OA-2000 and LENSTAR LS 900 have the same intended use: non-invasive, non-contact measurement of ocular parameters to determine IOL power for implantation. Both devices measure the same core parameters with equivalent ranges and accuracy. Technological differences between Fourier-domain vs. Time-domain do not raise new questions of safety or effectiveness, as both are an application of low-coherence interferometry. Clinical studies confirm equivalence in performance. The OA-2000 is substantially equivalent to the LENSTAR LS 900.

Classification	New Device: TOMEY OA-2000	Primary Predicate: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
Manufacturer	Tomey Corporation	Haag Streit AG	Not applicable
Classification	Class II	Class II	Same as predicate
Product Code	MXK - device, analysis, anterior segment	HJO - biomicroscope, slit-lamp, ac-powered	Same regulation as predicate
Subsequent Product Code	HJO - biomicroscope, slit-lamp, ac-powered		Same regulation as predicate
Regulation Number	21 CFR 886.1850	21 CFR 886.1850	Same as predicate
Regulation Name	AC-powered Slitlamp Biomicroscope	AC-powered Slitlamp Biomicroscope	Same as predicate

Classification	New Device: TOMEY OA-2000	Primary Predicate: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
Indications for Use	The Optical Biometer OA-2000 is a non-invasive, non-contact biometer intended for obtaining ocular measurements to assist in the determination of the appropriate power of an intraocular lens for implantation. The OA-2000 measures: Axial length, corneal thickness, anterior chamber depth and lens thickness.	The LENSTAR LS 900 is a non-invasive, non-contact OLCR (Optical Low Coherence Reflectometry) Biometer used for obtaining ocular measurements and performing calculations to assist in the determination of the appropriate power and type of IOL (intraocular lens) for implantation after removal of the natural crystalline lens following cataract removal. The LENSTAR LS 900 measures: *Axial eye length Corneal thickness Anterior chamber depth *Aqueous depth *Lens thickness *Radii of curvature of flat and steep meridian *Axis of the flat meridian *White to white distance *Pupil diameter	No new intended use; measurements align with the predicate (K082891), using optical interferometry. Differences from LENSTAR are immaterial, with no safety/effectiveness impact.
Technological Characteristics			
Measurement Ranges	Axial length: 14 to 33.5 mm,	Axial length: 14 to 32 mm,	There are minor differences in the measurement ranges between the OA-2000 and the predicate. The differences do not affect safety or effectiveness.
	Anterior chamber depth: 1.5 to 7.0 mm,	Anterior chamber depth: 1.5 to 6.5 mm,	
	Crystalline lens thickness: 0.5 to 6.0 mm,	Crystalline lens thickness: 0.5 to 6.5 mm,	
	Corneal thickness: 0.2 to 0.8 mm,	Corneal thickness: 300 to 800 um (0.3 to 0.8 mm),	

Classification	New Device: TOMEY OA-2000	Primary Predicate: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
	Corneal curvature radius: 5.0 to 11 mm,	Corneal curvature radius: 5 to 10.5 mm,	
	White-to-white distance: 7 to 16 mm,	White-to-white distance: 7 to 16 mm,	
	Pupil diameter: 1.5 to 13 mm	Pupil diameter: 2 to 13 mm	
Quantitative measurements	Provides the following measurements using optical interferometry technology: - Axial eye length - Corneal thickness - Anterior chamber depth - Lens thickness Provides the following measurements using keratometry rings: - Radii of curvature of flat and steep meridian - Axis of the flat meridian Provides the following measurements from the front image of the eye: - White to white distance - Pupil diameter	Provides the following measurements using optical coherence technology: - Axial eye length - Corneal thickness - Anterior chamber depth - Aqueous depth - Lens thickness Provides the following measurements using keratometry dots: - Radii of curvature of flat and steep meridian - Axis of the flat meridian Provides the following measurements from the front image of the eye: - White to white distance - Pupil diameter	Similar to predicate. Provides the same measurements. Method to obtain K values differs but does not result in significant differences because both methods analyze the reflection pattern from the corneal surface to estimate curvature.
Software	Supports IOL calculation formulas including Barrett Universal II, Haigis, Hoffer Q, Holladay 1, Olsen, SRK/T, Shammas-PL, and OKULIX (optional).	Supports IOL calculation formulas including Haigis, Hoffer Q, Holladay I, SRK/T, SRK II, and Olsen (via downloadable constants from Haag-Streit website).	Difference does not affect safety or effectiveness
Voltage and Frequency	100 to 240V AC 50 / 60Hz	100 to 240V AC 50 / 60Hz	Same as predicate

Classification	New Device: TOMEY OA-2000	Primary Predicate: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
Conclusion	The OA-2000 and LENSTAR LS 900 have the same intended use: non-invasive, non-contact measurement of ocular parameters to determine IOL power for implantation. Both devices measure the same core parameters with equivalent ranges and accuracy. Technological differences between placido ring (OA-2000) and keratometry dots (LS900) do not raise new questions of safety or effectiveness. Differences between Fourier-domain vs. Time-domain do not raise new questions of safety or effectiveness, as both are an application of low-coherence interferometry. Clinical studies confirm equivalence in performance. The OA-2000 is substantially equivalent to the LENSTAR LS 900.		

7. Non-Clinical and/or Clinical Tests Summary and Conclusions

Software documentation was provided as recommended by FDA's Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". Risk assessment regarding security and safety of the device was conducted in accordance with ISO 14971:2019.
Laser safety testing for the light sources used in OA-2000 were conducted to demonstrate compliance to ANSI Z80.36:2021.

Biocompatibility of the device was demonstrated by ISO 10993-1:2018.
Tests for electrical safety (IEC60601-1 Ed.3.2) and electromagnetic compatibility (IEC 60601-1-2 Ed.4.1) were performed. The OA-2000 device met the relevant requirements of the applied standards.

Clinical Testing:

This was a prospective comparative clinical study conducted at one clinical site located in the United States. Three OA-2000 Biometers and three LS900 devices were used. Two main types of analyses were performed: (1) agreement analysis, and (2) precision analysis.

Precision and agreement testing was performed. A total of 224 subjects were enrolled in the study, including 55 subjects in the normal group, 60 subjects in the cataract group, and 109 subjects in the special eyes (eyes without a natural lens or eyes containing artificial materials) group. All the subjects enrolled in the study completed the study. Therefore, the Safety Analysis Set and Full Analysis Set each comprised of 224 subjects. The clinical site had 3 device operators trained on the devices used in the study. The site was provided with 3 OA-2000 devices and 3 LenStar LS900 devices. Each OA-2000 device was paired with 1 of the LenStar LS900 devices and a device operator was assigned to each device pair to create 3 distinct operator/device configurations. Subjects were randomized to the device configuration sequences and to the starting device within each configuration. Each randomized subject was randomly assigned to one of the 3 configuration sequences:

- 1, 2, 3
- 2, 3, 1, or
- 3, 1, 2

Additional scans were taken at the operator's discretion if image quality was unacceptable based on the device DFU and the Tomey OA-2000 Reference Guide and included, missing scans, truncated scans, image defocus, presence of eye blinks, eye motion, etc. Each device operator had up to 3 attempts to obtain an acceptable scan for each of the required scans.

Table 11: Summary of Acceptable and Unacceptable Scans for Each Device and/or Scan Type – Full Analysis Set

Device and/or Scan Type Category	Normal (N=55) n (%)	Cataract (N=60) n (%)	Special Eyes (N=109) n (%)	All Subjects (N=224) n (%)
OA-2000				
Number of Acceptable Scans	489	531	875	1895
Number of Unacceptable Scans	24	28	271	323
Number of Subjects with 9 Acceptable Scans	50 (90.9)	55 (91.7)	81 (74.3)	186 (83.0)
Number of Subjects with Any Unacceptable Scans	11 (20.0)	16 (26.7)	51 (46.8)	78 (34.8)
LS900				
Number of Acceptable Scans	482	524	721	1727
Number of Unacceptable Scans	67	62	819	948
Number of Subjects with 9 Acceptable Scans	49 (89.1)	56 (93.3)	57 (52.3)	162 (72.3)
Number of Subjects with Any Unacceptable Scans	19 (34.5)	13 (21.7)	81 (74.3)	113 (50.4)
Note: N in the headers represented the total number of subjects enrolled in each respective subject population group. Percentages were based on the total number of subjects in each population group.				

Population characteristics:

The mean (SD) age in the Full Analysis Set was 34.7 (9.53) years for the normal subjects, 63.6 (9.73) years for the cataract subjects, and 69.2 (10.23) years for the special eye subjects. The overall mean age for all subjects was 59.2 (17.33) years, with the majority of subjects aged <65 years old (n = 113, 50.4%). All the subjects had age < 65 years (n = 55, 100%) in normal group, while majority of subjects aged >= 65 years in cataract group (n = 31, 61.7%) and special eyes group (n = 80, 73.4%) respectively. A total of 100 males, 123 females, and 1 unreported gender participated (44.6%, 54.9%, and 0.4% respectively) in this study, and the majority of subjects were white (n = 180, 80.4%) and not Hispanic or Latino (n = 181, 80.8%).

The study subject population included a full range of central corneal thickness (CCT) and anterior chamber depth (ACD). The normal range of CCT is generally depicted as 524 µm (0.524 mm) to 564 µm (0.564 mm) and the study population included a range of 410 to 655, with more than 25% of subjects below the normal range and more than 25% of subjects above the normal range based upon the LS900 measurement for the first configuration. For ACD, the vast majority of measurements in the special eyes group exceeded 4 mm, and ~10% subjects in the normal and cataract eye groups combined have ACD values less than 3 mm based upon the LS900 measurement for the first configuration.

Safety Evaluation:

There were no adverse events reported in this study. The subjects of this study had no notable or unexpected/untoward assessments for the safety measurements for visual acuity, undilated fundus, and intraocular pressure. Two subjects in the special eyes group experienced abnormal clinically significant (CS) findings in the slit lamp examination during the study. One subject had a CS finding of arcus senilis in the cornea in the right eye. A separate subject had a CS finding of ptosis in the eyelid in the left eye. Both the subjects completed the study.

Effectiveness:

This study evaluated the agreement and precision of the OA-2000 device with the LENSTAR, MODEL LS900 (K082891) as the predicate device.

Agreement:

Five (5) endpoints, including central corneal thickness (CCT), anterior chamber depth (ACD), optical axial length (AL), immersion-equivalent axial length (ALI) and lens thickness for agreement analysis between OA-2000 versus LS900 in each of the cohort including pooled population (or all subjects), normal subjects, cataract subjects, and subjects with special eyes are summarized in Table 15. ALI parameter was added as this was the best OA-2000 comparison with LS900 and calculated as a part of *Ad-hoc* analyses.

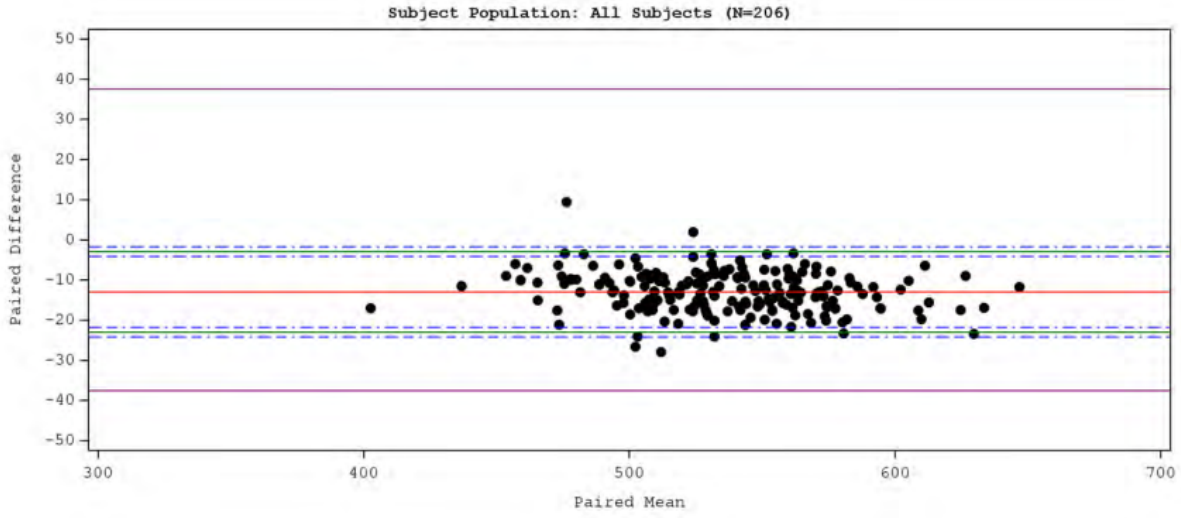
Table 1 Summary of the Limits of Agreement - OA-2000 (Test) versus LS900 (Predicate) – Agreement Analysis Set

Configuration Parameter (Unit)	N	OA-2000 Mean (SD)	LS900 Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
Subject Population: All Subjects (N=224)							
All Configurations							
Central Corneal Thickness (µm)	206	529.54 (38.909)	542.51 (39.959)	-12.97 (5.100)	(-23.03, -2.91)	(-24.24, -21.81)	(-4.13, -1.70)
Anterior Chamber Depth (mm)	195	4.02 (0.770)	4.06 (0.839)	-0.04 (0.296)	(-0.62, 0.54)	(-0.70, -0.55)	(0.47, 0.61)
Optical Axial Length (mm)	206	24.67 (1.371)	24.39 (1.441)	0.28 (0.092)	(0.10, 0.46)	(0.08, 0.12)	(0.44, 0.48)
Immersion-Equivalent Axial Length (mm)	206	24.38 (1.432)	24.39 (1.441)	-0.01 (0.061)	(-0.13, 0.11)	(-0.15, -0.12)	(0.10, 0.12)
Lens Thickness (mm)	195	2.76 (1.765)	2.75 (1.697)	0.01 (0.217)	(-0.41, 0.44)	(-0.47, -0.36)	(0.39, 0.50)
Subject Population: Normal (N=55)							
All Configurations							
Central Corneal Thickness (µm)	54	523.02 (39.920)	535.94 (39.938)	-12.92 (5.077)	(-23.10, -2.73)	(-25.50, -20.70)	(-5.13, -0.33)
Anterior Chamber Depth (mm)	54	3.60 (0.306)	3.60 (0.336)	0.00 (0.090)	(-0.18, 0.19)	(-0.22, -0.13)	(0.14, 0.23)
Optical Axial Length (mm)	54	24.38 (1.058)	24.07 (1.111)	0.30 (0.063)	(0.18, 0.43)	(0.15, 0.21)	(0.40, 0.46)
Immersion-Equivalent Axial Length (mm)	54	24.07 (1.106)	24.07 (1.111)	0.00 (0.035)	(-0.07, 0.07)	(-0.09, -0.05)	(0.06, 0.09)
Lens Thickness (mm)	54	3.90 (0.297)	3.81 (0.315)	0.09 (0.118)	(-0.15, 0.32)	(-0.20, -0.09)	(0.27, 0.38)
Subject Population: Cataract (N=60)							
All Configurations							

Configuration Parameter (Unit)	N	OA-2000 Mean (SD)	LS900 Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
Central Corneal Thickness (µm)	59	532.56 (34.344)	545.95 (35.555)	-13.40 (4.240)	(-21.88, -4.91)	(-23.80, -19.97)	(-6.82, -2.99)
Anterior Chamber Depth (mm)	59	3.35 (0.349)	3.34 (0.351)	0.02 (0.029)	(-0.04, 0.08)	(-0.05, -0.03)	(0.06, 0.09)
Optical Axial Length (mm)	59	24.54 (1.099)	24.23 (1.176)	0.30 (0.119)	(0.06, 0.54)	(0.01, 0.12)	(0.49, 0.60)
Immersion-Equivalent Axial Length (mm)	59	24.24 (1.147)	24.23 (1.176)	0.01 (0.096)	(-0.19, 0.20)	(-0.23, -0.14)	(0.16, 0.24)
Lens Thickness (mm)	59	4.53 (0.350)	4.47 (0.338)	0.06 (0.038)	(-0.01, 0.14)	(-0.03, 0.00)	(0.12, 0.16)
Subject Population: Special Eyes (N=109)							
All Configurations							
Central Corneal Thickness (µm)	93	531.42 (40.955)	544.15 (42.501)	-12.73 (5.622)	(-23.90, -1.57)	(-25.90, -21.89)	(-3.57, 0.44)
Anterior Chamber Depth (mm)	82	4.78 (0.500)	4.89 (0.541)	-0.11 (0.440)	(-0.99, 0.76)	(-1.16, -0.82)	(0.59, 0.93)
Optical Axial Length (mm)	93	24.92 (1.629)	24.67 (1.700)	0.25 (0.077)	(0.09, 0.40)	(0.07, 0.12)	(0.37, 0.43)
Immersion-Equivalent Axial Length (mm)	93	24.64 (1.702)	24.67 (1.700)	-0.03 (0.033)	(-0.10, 0.04)	(-0.11, -0.08)	(0.02, 0.05)
Lens Thickness (mm)	82	0.75 (0.241)	0.82 (0.265)	-0.07 (0.300)	(-0.67, 0.53)	(-0.78, -0.55)	(0.41, 0.64)

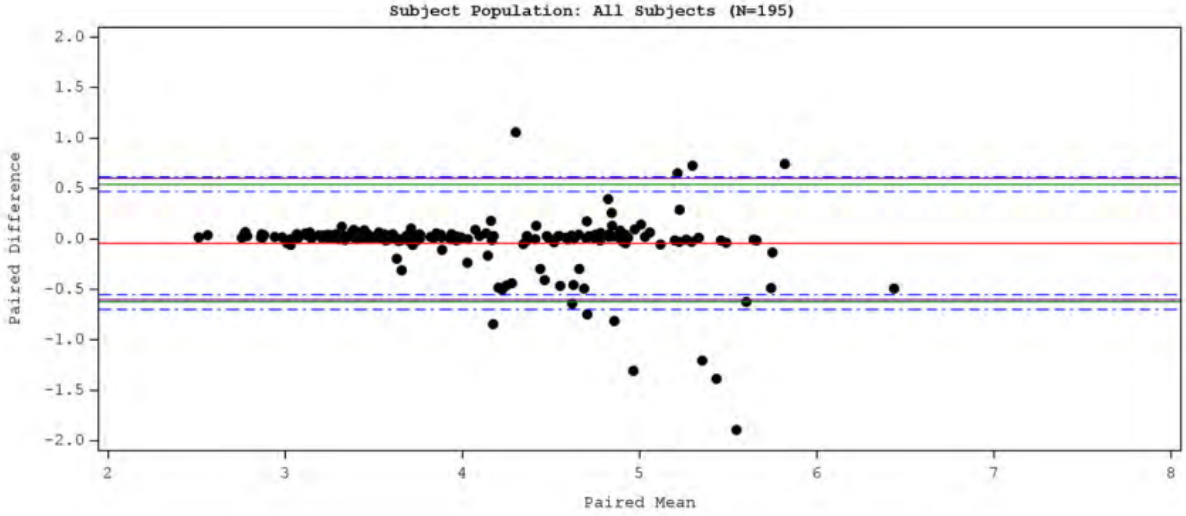
Abbreviations: CI = Confidence Interval; D = Diopters; µm = microns; mm = millimeter, SD = Standard Deviation.
Note: The Agreement Analysis Set used the first acceptable paired (from both devices) scans for analyses. N was the number of eyes with acceptable scans in the Agreement Analysis Set. Mean Difference was calculated as test minus predicate device (OA-2000 – LS900). The SD of the Mean Difference was based on paired t-test differences. Limits of Agreement (LOA) are calculated as Mean Difference +/- t x Mean Difference SD, where t was the critical value from t-distribution with n-1 degrees of freedom. The 95% CI on the upper and lower bounds of the LOA were calculated as: LOA ± t x (SQRT(3/n) x s); t is the 97.5% critical value of the t distribution with n-1 degrees of freedom, s was the standard deviation, and n was the number of subjects. Axial length immersion parameter was calculated as part of ad-hoc analyses.

Figure 14.4.1.4
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for OA-2000 (Test) and LS900 (Predicate) for Central Corneal Thickness (µm)
Agreement Analysis Set



Note: The Paired Differences are calculated as (OA-2000 - LS900). Paired Means are calculated as (OA-2000 + LS900)/2. The red horizontal line is the mean of the Paired Differences. The green horizontal lines are the 95% Limits of Agreement (LOAs). Blue dashed lines are the associated 95% Confidence Intervals around the LOAs. The purple lines are the performance bounds for each population.

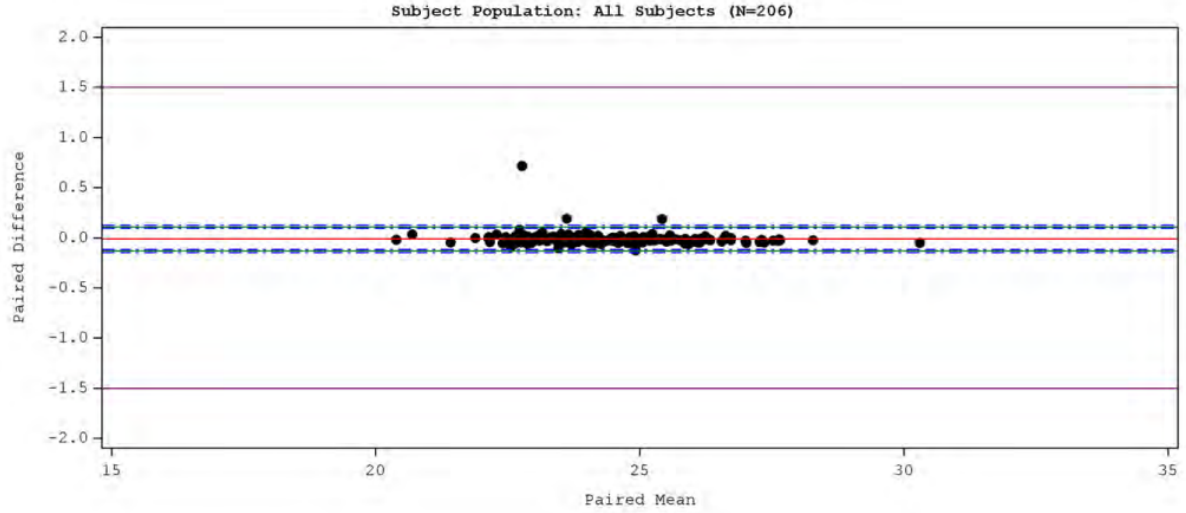
Figure 14.4.1.5
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for OA-2000 (Test) and LS900 (Predicate) for Anterior Chamber Depth (mm)
Agreement Analysis Set



Note: The Paired Differences are calculated as (OA-2000 - LS900). Paired Means are calculated as (OA-2000 + LS900)/2. The red horizontal line is the mean of the Paired Differences. The green horizontal lines are the 95% Limits of Agreement (LOAs). Blue dashed lines are the associated 95% Confidence Intervals around the LOAs. The purple lines are the performance bounds for each population.

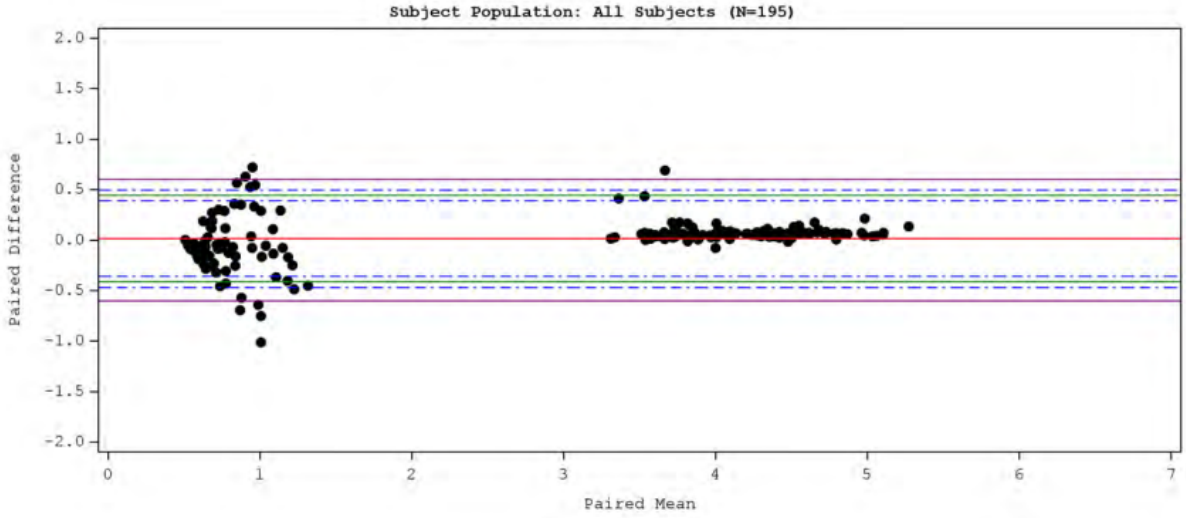
Figure 14.4.1.18 shows a comparison of OA-2000 immersion-equivalent axial length to the LS-900 immersion-equivalent axial length.

Figure 14.4.1.18
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for OA-2000 (Test) and LS900 (Predicate) for Axial Length (mm) using Axial Immersion Average for OA-2000
Agreement Analysis Set



Note: The Paired Differences are calculated as (OA-2000 - LS900). Paired Means are calculated as (OA-2000 + LS900)/2. The red horizontal line is the mean of the Paired Differences. The green horizontal lines are the 95% Limits of Agreement (LOAs). Blue dashed lines are the associated 95% Confidence Intervals around the LOAs. The purple lines are the performance bounds for each population.
Reference: Table 14.2.1.1.18
Source: P:\projects\tomey\oa-2000-001_3_23\Statistics\CSR\Primary Programs\TLF\f_bland1_ai.sas 20DEC2024 9:55:03

Figure 14.4.1.7
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for OA-2000 (Test) and LS900 (Predicate) for Lens Thickness (mm)
Agreement Analysis Set



Note: The Paired Differences are calculated as (OA-2000 - LS900). Paired Means are calculated as (OA-2000 + LS900)/2. The red horizontal line is the mean of the Paired Differences. The green horizontal lines are the 95% Limits of Agreement (LOAs). Blue dashed lines are the associated 95% Confidence Intervals around the LOAs. The purple lines are the performance bounds for each population.

Precision Study:

Five (5) endpoints, including CCT, ACD, AL, ALI, and LT for precision analysis between OA-2000 versus LS900 in each of the cohort including pooled population (or all subjects), normal subjects, cataract subjects, and subjects with special eyes are summarized in Table 28. ALI parameter was added

as this was the best OA-2000 comparison with LS900 and calculated as part of ad-hoc analyses. For the precision analysis between OA-2000, and LS900, repeatability %CV and reproducibility % CV for the OA-2000 parameters CCT, ACD, AL, and LT in the normal subjects and cataract subjects were less than their respective stated performance goals. Moreover, the ratios of the variation components for most of the parameters were found to be less than 1, indicating that OA-2000 was less variable. Overall, the OA-2000 device had acceptable variation based on repeatability among the parameters CCT, ACD, AL, and LT in normal subjects; CCT, ACD, AL, and LT in cataract subjects; and CCT and AL in pooled population (or all subjects) and subjects with special eyes.

Additionally, OA-2000 test device and LS900 predicate device also had acceptable variation based on reproducibility among the parameters CCT and AL in pooled population (or all subjects) and subjects with special eyes; the parameters CCT, ACD, AL, and LT in normal subjects; and the parameters CCT, ACD, AL, and LT in cataract subjects.

Table 2 Summary of Repeatability and Reproducibility - OA-2000 (Test) versus LS900 (Predicate) - Precision Analysis Set

			Repeatability			Reproducibility		
Device Parameter (unit)	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Subject Population: All Subjects (N=224)								
OA-2000								
Central Corneal Thickness (µm)	126	532.88	0.77%	0.73%	0.81%	0.87%	0.84%	0.91%
Anterior Chamber Depth (mm)	120	3.813	2.75%	2.61%	2.90%	3.02%	2.89%	3.16%
Optical Axial Length (mm)	126	24.591	0.08%	0.07%	0.08%	0.09%	0.09%	0.10%
Immersion-Equivalent Axial Length (mm)	126	24.298	0.08%	0.08%	0.09%	0.10%	0.09%	0.10%
Lens Thickness (mm)	118	3.262	2.59%	2.46%	2.73%	8.70%	8.32%	9.11%
LS900								
Central Corneal Thickness (µm)	126	545.823	0.37%	0.35%	0.39%	0.54%	0.52%	0.57%
Anterior Chamber Depth (mm)	120	3.828	2.77%	2.63%	2.92%	3.18%	3.04%	3.33%
Optical Axial Length (mm)	126	24.31	0.06%	0.06%	0.07%	0.08%	0.08%	0.08%
Immersion-Equivalent Axial Length (mm)	126	24.31	0.06%	0.06%	0.07%	0.08%	0.08%	0.08%
Lens Thickness (mm)	118	3.191	2.47%	2.34%	2.60%	3.46%	3.31%	3.63%
Subject Population: Normal (N=55)								
OA-2000								
Central Corneal Thickness (µm)	41	529.967	0.82%	0.76%	0.90%	0.95%	0.88%	1.03%
Anterior Chamber Depth (mm)	40	3.584	0.55%	0.51%	0.60%	0.75%	0.70%	0.82%
Optical Axial Length (mm)	41	24.233	0.09%	0.08%	0.09%	0.09%	0.09%	0.10%
Immersion-Equivalent Axial Length (mm)	41	23.924	0.09%	0.08%	0.10%	0.10%	0.09%	0.11%

			Repeatability			Reproducibility		
Device Parameter (unit)	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Lens Thickness (mm)	38	3.878	0.63%	0.57%	0.69%	0.73%	0.67%	0.79%
LS900								
Central Corneal Thickness (µm)	41	542.632	0.41%	0.37%	0.45%	0.68%	0.63%	0.74%
Anterior Chamber Depth (mm)	40	3.566	0.84%	0.77%	0.92%	1.48%	1.38%	1.61%
Optical Axial Length (mm)	41	23.924	0.06%	0.05%	0.06%	0.08%	0.07%	0.08%
Immersion-Equivalent Axial Length (mm)	41	23.924	0.06%	0.05%	0.06%	0.08%	0.07%	0.08%
Lens Thickness (mm)	38	3.803	1.07%	0.98%	1.18%	2.47%	2.29%	2.68%
Subject Population: Cataract (N=60)								
OA-2000								
Central Corneal Thickness (µm)	48	534.347	0.75%	0.70%	0.82%	0.84%	0.79%	0.90%
Anterior Chamber Depth (mm)	47	3.386	0.39%	0.36%	0.42%	0.53%	0.49%	0.57%
Optical Axial Length (mm)	48	24.647	0.05%	0.04%	0.05%	0.05%	0.05%	0.06%
Immersion-Equivalent Axial Length (mm)	48	24.357	0.05%	0.04%	0.05%	0.06%	0.05%	0.06%
Lens Thickness (mm)	47	4.518	0.48%	0.44%	0.52%	0.55%	0.51%	0.59%
LS900								
Central Corneal Thickness (µm)	48	547.471	0.32%	0.30%	0.35%	0.47%	0.44%	0.51%
Anterior Chamber Depth (mm)	47	3.37	0.88%	0.82%	0.96%	1.48%	1.38%	1.59%
Optical Axial Length (mm)	48	24.361	0.06%	0.06%	0.07%	0.08%	0.07%	0.09%
Immersion-Equivalent Axial Length (mm)	48	24.361	0.06%	0.06%	0.07%	0.08%	0.07%	0.09%
Lens Thickness (mm)	47	4.434	0.86%	0.79%	0.93%	1.94%	1.81%	2.09%
Subject Population: Special Eyes (N=109)								
OA-2000								
Central Corneal Thickness (µm)	37	534.204	0.72%	0.65%	0.79%	0.83%	0.77%	0.90%
Anterior Chamber Depth (mm)	33	4.7	4.21%	3.83%	4.67%	4.61%	4.25%	5.04%
Optical Axial Length (mm)	37	24.914	0.10%	0.09%	0.11%	0.12%	0.11%	0.13%
Immersion-Equivalent Axial Length (mm)	37	24.636	0.11%	0.10%	0.12%	0.13%	0.12%	0.14%
Lens Thickness (mm)	33	0.764	20.32%	18.46%	22.61%	69.96%	62.68%	79.23%
LS900								
Central Corneal Thickness (µm)	37	547.22	0.39%	0.35%	0.43%	0.45%	0.42%	0.49%
Anterior Chamber Depth (mm)	33	4.8	4.09%	3.72%	4.54%	4.51%	4.16%	4.93%

			Repeatability			Reproducibility		
Device Parameter (unit)	**N**	**Overall Mean**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**	**%CV**	**%CV Lower 95% CI**	**%CV Upper 95% CI**
Optical Axial Length (mm)	37	24.673	0.07%	0.07%	0.08%	0.09%	0.08%	0.10%
Immersion-Equivalent Axial Length (mm)	37	24.673	0.07%	0.07%	0.08%	0.09%	0.08%	0.10%
Lens Thickness (mm)	33	0.715	18.85%	17.13%	20.97%	21.17%	19.45%	23.23%

Abbreviations: CI = Confidence Interval; CV = Coefficient of Variation; mm = millimeters, µm = microns.
Note: The Precision Analysis Set used subjects with 9 acceptable scans per device. N was the number of eyes with acceptable scans in the Precision Analysis Set. The crossed analysis model was used to calculate reproducibility limits, and repeatability limits included configuration, subject, and configuration x subject interaction as variance components using restricted maximum likelihood method (REML) for estimation. The repeatability limit was 2.8 times the repeatability SD, which was the square root of the residual within subject variance component. The reproducibility limit was 2.8 times the reproducibility SD, which was the square root of the sum of the variance components of configuration, configuration x subject interaction and residual within subject. CV% was calculated as the Repeatability or Reproducibility SD/Overall Mean. Axial length immersion parameter was calculated as part of ad-hoc analyses.

Measurements of ACD and lens thickness have not been validated for agreement with other devices in subjects with eyes with an IOL, silicone oil or any other eyes except phakic eyes. This device should not be used in such eyes if ACD or lens thickness is a critical value that impacts clinical management.

8. Conclusion

Therefore, based on the same intended use and similar technological characteristics with substantial equivalence to the reference device confirmed with performance testing, the Tomey OA-2000 is technologically and functionally equivalent to the predicate device, LENSTAR, MODEL LS900 (K082891). The differences between the proposed device, OA-2000, and the predicate device are not significant and do not raise new issues of safety or effectiveness of the device. The Tomey OA-2000 is as safe and effective as its predicate device and thus may be considered substantially equivalent.