July 18, 2025

TOMEY Corporation
% Roger Albright
Associate Director, Medical Devices
Ora Inc.
138 Haverhill Street, Suite 102
Andover, Massachusetts 01810

Re: K250553
Trade/Device Name: Tomey Cornea/Anterior Segment OCT (CASIA2)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: February 25, 2025
Received: February 25, 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)*
K250553

Device Name
Tomey Cornea/Anterior Segment OCT (CASIA2)

Indications for Use *(Describe)*
CASIA2 is a non-contact, high-resolution tomographic and biomicroscopic device intended for the in vivo imaging and measurement of ocular structures in the anterior segment. CASIA2 measures 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 Cornea/Anterior Segment OCT CASIA2 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

July 8, 2025

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

Trade Name:	Tomey Cornea/Anterior Segment OCT (CASIA2)
Common Name:	Ophthalmoscope.
Classification Name:	Tomography, optical coherence
Product Code:	OBO
Classification Regulation:	21 CFR 886.1570

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

The CASIA2 is substantially equivalent to the following legally marketed device:

510(k) Number	Trade name	Product code
K213265	Cornea/Anterior Segment OCT CASIA2	OBO

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

The Tomey Cornea/Anterior Segment OCT CASIA2 (CASIA2) is a non-contact, high resolution tomographic and biomicroscopic device indicated for in vivo imaging of ocular structures in the anterior

segment. The Tomey Cornea/Anterior Segment OCT CASIA2 is indicated as an aid in the visualization and measurement of anterior segment findings. CASIA2 measures corneal thickness, anterior chamber depth and lens thickness.

This medical device product has functions subject to FDA premarket review (corneal thickness, curvature, anterior chamber depth and lens thickness) as well as functions that are not subject to FDA premarket review. For this application, for the (510(k) exempt functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the overall device.

CASIA2 consists of several components: the main unit, AC input power source, a touch panel LCD monitor, an external hard drive (HDD), a mouse and a keyboard.

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

CASIA2 is a non-contact, high-resolution tomographic and biomicroscopic device intended for the in vivo imaging and measurement of ocular structures in the anterior segment. CASIA2 measures corneal thickness, anterior chamber depth and lens thickness.

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

The CASIA2 maintains the same intended use as the predicate CASIA2 (K213265) in vivo imaging and measurement of anterior segment ocular structures using identical swept-source OCT technology (1310 nm, 50,000 A-scans/s). It adds quantitative outputs (e.g., corneal thickness, curvature, anterior chamber depth and lens thickness) that align with K213265's capabilities, with no new intended use or safety/effectiveness risks. While some outputs overlap with LENSTAR LS900 (K082891) as a reference device, CASIA2 omits axial length and uses OCT, not optical low coherence reflectometry (OLCR), with no new concerns raised.

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

The device is a software upgraded version of the predicate K213265 that provides quantitative measurements. All quantitative measurements are derived from OCT images acquired with optical coherence tomography. This is the same technology used in the reference device K082891 utilizes to acquire measurements of various ocular structures of the eye.

Classification	New Device: Tomey CASIA2 with Updated Software	Primary Predicate: Tomey Cornea/Anterior Segment OCT CASIA2 (K213265)	Reference Device: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
Manufacturer	Tomey Corporation	Tomey Corporation	Haag Streit	Same as predicate
Classification	Class II	Class II	Class II	Same as both predicate and reference
Product Code	OBO	OBO	HJO	Same as predicate
Regulation Number	21 CFR 886.1570	21 CFR 886.1570	21 CFR 886.1850	Same as predicate
Regulation Name	Ophthalmoscope	Ophthalmoscope	AC-powered Slitlamp Biomicroscope	Same as predicate
Indications for Use	CASIA2 is a non-contact, high-resolution tomographic and biomicroscopic device intended for the in vivo imaging and measurement of ocular structures in the anterior segment. CASIA2 measures corneal thickness, anterior chamber depth and lens thickness.	The Tomey Cornea/Anterior Segment OCT CASIA2 is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging of ocular structures in the anterior segment. The Tomey Cornea/Anterior Segment OCT CASIA2 is indicated as an aid in the visualization of anterior segment findings.	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 K213265's imaging, using identical swept-source OCT. Differences from LENSTAR (OCT vs. OLCR, no axial length) are immaterial, focusing on anterior segment, with no safety/effectiveness impact.
Technological Characteristics				
- OCT Imaging	Swept Source OCT	Swept Source OCT	Optical Low Coherence Reflectometry (OLCR)	Same as predicate

Classification	New Device: Tomey CASIA2 with Updated Software	Primary Predicate: Tomey Cornea/Anterior Segment OCT CASIA2 (K213265)	Reference Device: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
- Scan Rate	50,000 A-Scan/s	50,000 A-Scan/s	Unknown	Same as predicate
- Wavelength	1310 nm	1310 nm	820 nm for eye length, 950 nm for keratometry	Same as predicate
- Power Output	<6 mW	<6 mW	<0.6 mW for eye length, not specified for keratometry	Same as predicate
- Field of View/Measurement Range	Depth: 13mm Transverse: Radial scan: 16 mm, Raster scan: 12mm x 12mm	Depth: 13mm Transverse: Radial scan: 16 mm, Raster scan: 12mm x 12mm	N/A	Same as predicate
- Focus Range	-18 D to +15 D	-18 D to +15 D	Not specified	Same as predicate
Software	Updated for quantitative measurements	Existing software	Not detailed	Same as predicate; new outputs (e.g., CCT, ACD) derived from K213265's OCT images, no new risks.
Measures Axial Length	No	No	Yes	Same as predicate; omission vs. LENSTAR immaterial, focuses on anterior segment, no safety impact.
Obtains radiii of curvature of flat and steep meridians and axis of the flat meridian and steep meridian	Uses Swept Source OCT Technology	N/A. Does not obtain measurements	Uses keratometry dots	Similar to reference device. Both devices obtain radii of curvature of flat and steep merdians and axis of the flat merdian and steep meridian
Image Display / Scan Types	Visualizes the anterior segment structures by OCT technology.	Visualizes the anterior segment structures by OCT technology.	Provides front image of the eye	Same as Predicate
Qualitative imaging	Visualizes the anterior segment of the eye such as the cornea, anterior chamber, angle, iris, and lens by OCT technology. Also provides the front image of the eye.	Visualizes the anterior segment of the eye such as the cornea, anterior chamber, angle, iris, and lens by OCT technology. Also provides the front image of the eye.	Provides the front image of the eye	Same as Predicate

Classification	New Device: Tomey CASIA2 with Updated Software	Primary Predicate: Tomey Cornea/Anterior Segment OCT CASIA2 (K213265)	Reference Device: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
Quantitative measurements	Similarities with Secondary Predicate Device: The subject device provides the following measurements using OCT imaging, which is visualized images derived from signals using optical coherence technology as the secondary predicate: - Corneal thickness - Anterior chamber depth - Aqueous depth (provided as “ACD(Endo)”) - Lens thickness The subject device provides the following measurements using the front image of the eye: - White to white distance - Pupil diameter Differences The subject device does not provide the axial length, unlike the secondary predicate. The subject device uses OCT technology to **obtain the radii of curvature of flat and steep meridian and axis of the flat meridian and steep meridian**, while the secondary predicate utilizes keratometry dots. Agreement between devices were confirmed in a clinical study.	None	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	No new risks; outputs use K213265’s OCT, matching LENSTAR where applicable, with no safety/effectiveness impact.

Classification	New Device: Tomey CASIA2 with Updated Software	Primary Predicate: Tomey Cornea/Anterior Segment OCT CASIA2 (K213265)	Reference Device: LENSTAR, MODEL LS900 (K082891)	Discussion Analysis of Differences Affect Safety or Effectiveness
Resolution	Axial: 10μm or less (in tissue) Transverse: 30μm or less (in air)	Axial: 10μm or less (in tissue) Transverse: 30μm or less (in air)	N/A	Same as Predicate
Voltage and Frequency	100 to 240V AC 50 / 60Hz	100 to 240V AC 50 / 60Hz	100 to 240V AC 50 / 60Hz	Same
Conclusion				The subject device has the same hardware as its predicate, Cornea/Anterior Segment OCT CASIA2 (K213265). The subject device has updated software to provide quantitative measurements, including CCT, ACD, and LT evaluated against LENSTAR, MODEL LS900 (K082891) in a clinical study, with no new safety or effectiveness risks.

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 inMedical 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 CASIA2 were conducted to demonstrate compliance to ANSI Z80.36:2021.

Bench tests were conducted to verify, OCT specifications such as axial and transverse resolution, accuracy of transverse length and accuracy of angle. The device met all predetermined acceptance criteria.

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 CASIA2 device met the relevant requirements of the applied standards.

Clinical Testing:

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 CASIA2 devices and 3 LenStar LS900 devices. Each CASIA2 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 CASIA2 Reference Guide and included, missing scans, truncated scans, image defocus, floaters, 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.

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 CASIA2 OCT device with the CASIA2 (K213265) as the predicate device and the LENSTAR, MODEL LS900 (K082891) as the reference device.

Agreement:

CASIA2 Corneal Map Scan – Two (2) endpoints (CCT and ACD) for agreement analysis between CASIA2 corneal map compared to 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 18.

Table 18. Summary of the Limits of Agreement - CASIA2 Corneal Map (test) versus LS900 (Predicate) - Agreement Analysis Set

Configuration Parameter (Unit)	N	CASIA2 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	536.18 (38.533)	542.19 (39.983)	-6.01 (3.767)	(-13.44, 1.42)	(-14.33, -12.54)	(0.52, 2.31)
Anterior Chamber Depth (µm)	201	4.14 (0.774)	4.10 (0.854)	0.04 (0.354)	(-0.66, 0.74)	(-0.74, -0.57)	(0.66, 0.83)
Subject Population: Normal (N=55)							
All Configurations							
Central Corneal Thickness (µm)	54	529.69 (38.883)	535.87 (40.0240	-6.19 (4.344)	(-14.90, 2.52)	(-16.95, -12.85)	(0.47, 4.58)
Anterior Chamber Depth (µm)	54	3.68 (0.319)	3.60 (0.336)	0.08 (0.097)	(-0.11, 0.28)	(-0.16, -0.07)	(0.23, 0.32)
Subject Population: Cataract (N=60)							
All Configurations							
Central Corneal Thickness (µm)	59	539.97 (34.225)	545.95 (35.549)	-5.98 (2.975)	(-11.94, -0.03)	(-13.28, -10.59)	(-1.37, 1.32)
Anterior Chamber Depth (µm)	59	3.43 (0.357)	3.34 (0.351)	0.09 (0.025)	(0.04, 0.14)	(0.03, 0.06)	(0.13, 0.15)
Subject Population: Special Eyes (N=109)							
All Configurations							
Central Corneal Thickness (µm)	93	537.55 (40.782)	543.47 (42.527)	-5.92 (3.892)	(-13.65, 1.81)	(-15.04, -12.26)	(0.42, 3.20)
Anterior Chamber Depth (µm)	88	4.90 (0.415)	4.91 (0.550)	-0.01 (0.526)	(-1.06, 1.03)	(-1.25, -0.87)	(0.84, 1.23)

Abbreviations: CI = Confidence Interval, D = Diopter, µm = microns, mm = millimeters, SD = Standard Deviation

Note: The Agreement Analysis set used the first acceptable paired (from both devices) scans for analysis. N was the number of eyes with acceptable scans in the agreement Analysis Set. Mean Difference was calculated as test minus predicate device (CASIA2-LS900). The SD of the Mean Difference was based on paired t-test differences. Limits of Agreement (LOA) were 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 of the upper and lower bounds of the LOA were calculated as: LOA $\pm$ t x (SQRT(3/n) x s; t was 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.

Reference: Table 14.2.1.2.2, Listing 16.2.6.2, 16.2.6.4.

Figure 14.4.1.12
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for CASIA2 Cornea Map (Test) and LS900 (Predicate) for Central Corneal Thickness (µm)
Agreement Analysis Set

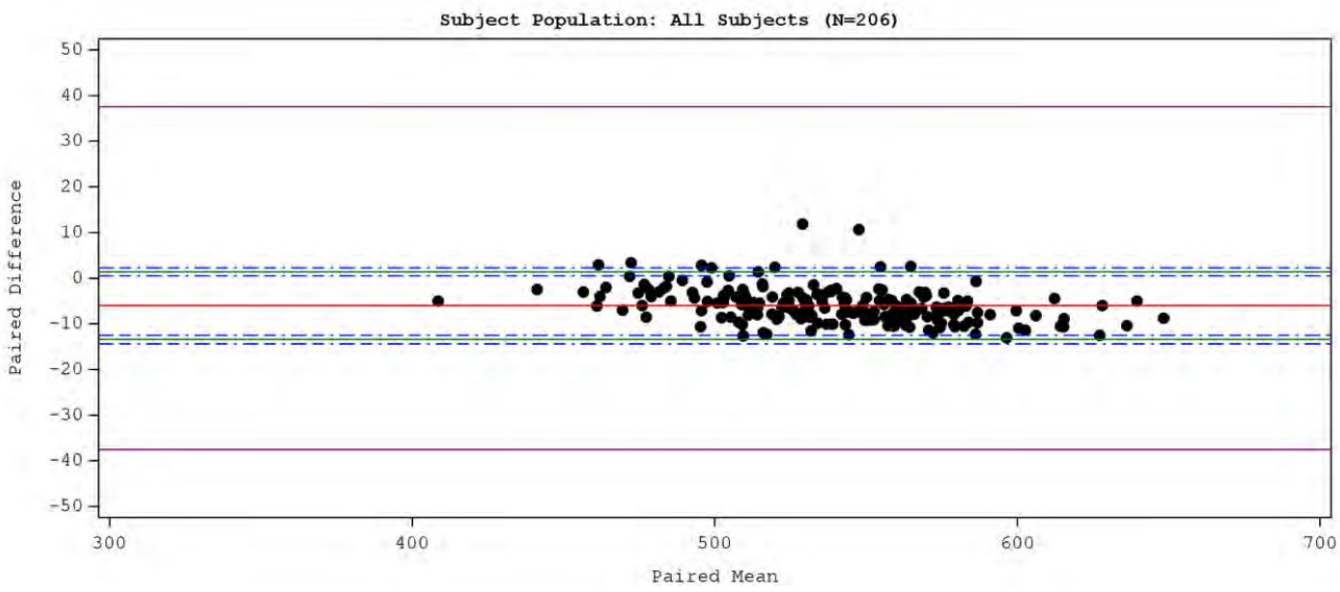
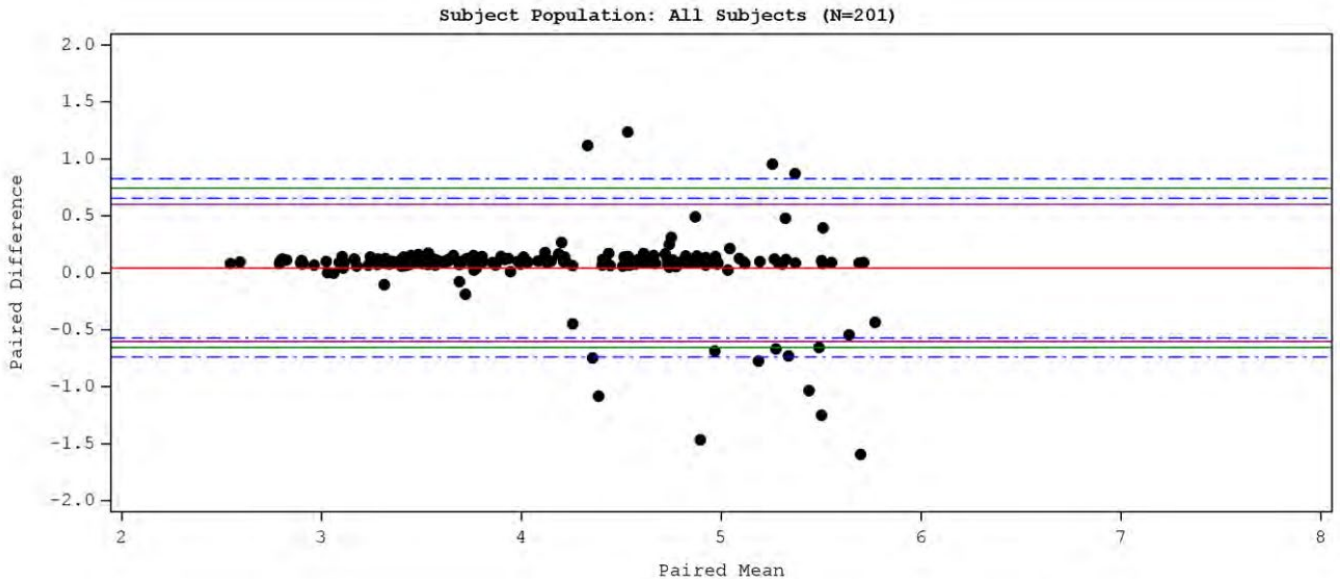


Figure 14.4.1.13
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for CASIA2 Cornea Map (Test) and LS900 (Predicate) for Anterior Chamber Depth (mm)
Agreement Analysis Set



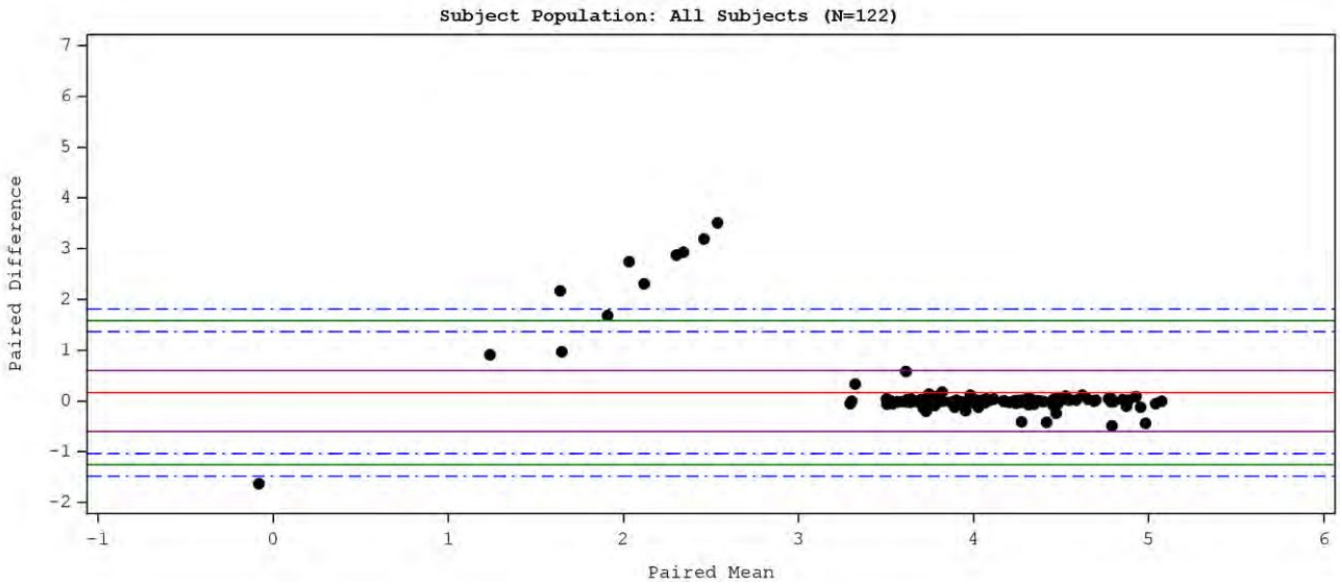
CASIA2 Lens scan. The endpoint, lens thickness (LT) for agreement analysis between CASIA2 Lens scan and LS900 is summarized in Table 21.

Table 21 Summary of the Limits of Agreement - CASIA2 Lens Scan (Test) versus LS900 (Predicate) – Agreement Analysis Set

	N	CASIA2 Mean (SD)	LS900 Mean (SD)	Mean Difference (SD)	95% LOA	95% CI Lower LOA	95% CI Upper LOA
Lens Thickness (mm)							
Subject Population: All Subjects (N=224)							
All Configurations	122	4.03 (0.705)	3.86 (1.049)	0.16 (0.719)	(-1.26, 1.59)	(-1.48, -1.04)	(1.36, 1.81)
Subject Population: Normal (N=55)							
All Configurations	53	3.83 (0.304)	3.82 (0.310)	0.01 (0.112)	(-0.21, 0.24)	(-0.27, -0.16)	(0.18, 0.29)
Subject Population: Cataract (N=60)							
All Configurations	58	4.43 (0.328)	4.47 (0.338)	-0.04 (0.126)	(-0.29, 0.21)	(-0.35, -0.23)	(0.16, 0.27)
Subject Population: Special Eyes (N=109)							
All Configurations	11	2.82 (1.472)	0.85 (0.174)	1.97 (1.468)	(-1.30, 5.24)	(-3.01, 0.41)	(3.53, 6.95)

Abbreviations: CI = Confidence Interval; NC = Not Calculable; 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 (CASIA2 – LS900). The SD of the Mean Difference was based on paired t-test differences. Limits of Agreement (LOA) were 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 was the 97.5% critical value of the t distribution with n-1 degrees of freedom, was the standard deviation, and n was the number of subjects.
Reference: Table 14.2.1.2.3, Listing 16.2.6.3, 16.2.6.4.

Figure 14.4.1.14
Agreement Analysis - Bland Altman Plot of Observed Data (All Configurations) - Paired Difference Between Devices for CASIA2 Lens Thickness (Test) and LS900 (Predicate) for Lens Thickness (mm)
Agreement Analysis Set



Precision Study:

CASIA2 Corneal Map - Two (2) endpoints, CCT and ACD were evaluated for precision analysis between CASIA2 Corneal Map and LS900 in each cohort (pooled population of all subjects, normal subjects, cataract subjects, and subjects with special eyes) are summarized in Table 27.

Table 1 Summary of Repeatability and Reproducibility - CASIA2 Corneal Map (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)								
CASIA2								
Central Corneal Thickness (µm)	138	538.861	0.18%	0.17%	0.19%	0.32%	0.31%	0.33%
Anterior Chamber Depth (mm)	135	3.949	1.01%	0.97%	1.07%	1.13%	1.08%	1.18%
LS900								
Central Corneal Thickness (µm)	138	545.013	0.36%	0.34%	0.38%	0.53%	0.51%	0.56%
Anterior Chamber Depth (mm)	135	3.861	3.09%	2.94%	3.24%	4.35%	4.17%	4.54%
Subject Population: Normal (N=55)								
CASIA2								
Central Corneal Thickness (µm)	45	534.21	0.18%	0.17%	0.20%	0.33%	0.31%	0.36%
Anterior Chamber Depth (mm)	44	3.681	0.45%	0.42%	0.49%	0.82%	0.76%	0.89%
LS900								
Central Corneal Thickness (µm)	45	540.02	0.39%	0.36%	0.43%	0.66%	0.62%	0.71%
Anterior Chamber Depth (mm)	44	3.581	0.81%	0.74%	0.88%	1.41%	1.32%	1.53%
Subject Population: Cataract (N=60)								
CASIA2								
Central Corneal Thickness (µm)	54	543.053	0.17%	0.16%	0.18%	0.31%	0.29%	0.33%
Anterior Chamber Depth (mm)	53	3.459	0.15%	0.14%	0.16%	0.37%	0.35%	0.40%
LS900								
Central Corneal Thickness (µm)	54	549.29	0.32%	0.29%	0.34%	0.47%	0.44%	0.51%
Anterior Chamber Depth (mm)	53	3.368	0.86%	0.80%	0.94%	1.48%	1.38%	1.58%
Subject Population: Special Eyes (N=109)								
CASIA2								
Central Corneal Thickness (µm)	39	538.422	0.20%	0.18%	0.21%	0.32%	0.30%	0.35%
Anterior Chamber Depth (mm)	38	4.941	1.48%	1.35%	1.63%	1.54%	1.42%	1.67%
LS900								
Central Corneal Thickness (µm)	39	544.852	0.38%	0.35%	0.42%	0.45%	0.42%	0.49%
Anterior Chamber Depth (mm)	38	4.873	4.51%	4.13%	4.97%	6.29%	5.82%	6.83%

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.
Reference: Table 14.2.2.2.2, Listing 16.2.6.2, 16.2.6.4.

CASIA2 Lens scan. The endpoint lens thickness (LT) for precision analysis in each cohort is summarized in Table 28.

Table 28 Summary of Repeatability and Reproducibility - CASIA2 Lens Scan (Test) versus LS900 (Predicate) - Precision Analysis Set

			Repeatability			Reproducibility		
Device	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)								
Lens Thickness (mm)								
CASIA2	76	4.116	1.05%	0.99%	1.13%	1.39%	1.32%	1.48%
LS900	76	4.116	1.01%	0.95%	1.08%	2.35%	2.23%	2.49%
Subject Population: Normal (N=55)								
Lens Thickness (mm)								
CASIA2	36	3.798	0.85%	0.78%	0.94%	1.54%	1.42%	1.68%
LS900	36	3.782	1.02%	0.93%	1.12%	2.48%	2.30%	2.71%
Subject Population: Cataract (N=60)								
Lens Thickness (mm)								
CASIA2	40	4.403	1.16%	1.07%	1.28%	1.28%	1.19%	1.39%
LS900	40	4.417	1.00%	0.92%	1.10%	2.25%	2.08%	2.43%

Abbreviations: CI = Confidence Interval; CV = Coefficient of Variation, mm =millimeters.
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 include 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.
Reference: Table 14.2.2.2.3, Listing 16.2.6.3, 16.2.6.4.

Repeatability %CV and reproducibility %CV for CASIA2 Lens Scans could not be assessed for the special eye subjects due to unacceptable scans.

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 CASIA2 is technologically and functionally equivalent to the predicate device, Tomey CASIA2 (K213265) and the reference device LENSTAR, MODEL LS900 (K082891). The differences between the proposed device, CASIA2, and the predicate and reference device are not significant and do not raise new issues of safety or effectiveness of the device. The Tomey CASIA2 is as safe and effective as its predicate and reference devices, and thus may be considered substantially equivalent.