



December 23, 2025

Cylite Pty. Ltd.
% Michelle Ravert
Manager, Global Regulatory Affairs - Surgical
Alcon Research, LLC
20511 Lake Forest Dr
Lake Forest, California 92630

Re: K252633

Trade/Device Name: Unity Dx (udx)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HJO
Dated: November 10, 2025
Received: November 12, 2025

Dear Michelle Ravert:

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,

Alexander Beylin Date: 2025.12.23

-S 10:28:11 -05'00'

for Elvin Ng

Assistant Director

DHT1A: Division of Ophthalmic Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252633

?

Please provide the device trade name(s).

?

UNITY DX (UDX)

Please provide your Indications for Use below.

?

The Unity DX instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of anterior and posterior ocular structures and measurement of anterior segment and biometric parameters including:

- Axial Length
- Anterior Chamber Depth
- Central Corneal Thickness
- Lens Thickness

The Reference Image functionality is intended for use as an ocular image capture tool.

Please select the types of uses (select one or both, as applicable).

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

?

510(k) Summary

In accordance with 21 CFR 807.92, Alcon Research LLC., on behalf of Cylite Pty. Ltd., hereby provides the 510(k) summary for the UNITY™ DX Instrument.

1. SPONSOR / 510(k) OWNER / MANUFACTURER [per 807.92(a)(1)]

Applicant / Manufacturer	Cylite Pty. Ltd. 300 Wellington Road Mulgrave VIC 3170 Australia +61-3-95812601
Sponsor Contact	Arnold Ouyang Head Quality & Regulatory 300 Wellington Road Mulgrave Victoria 3170 Australia +61-3-95812601 arnold.ouyang@cyliteoptics.com
Official Correspondent	Michelle Ravert Regulatory Affairs Manager Alcon Research LLC, on behalf of Alcon Laboratories, Inc. 20511 Lake Forest Drive Lake Forest, CA 92630-7741 +1 (610) 715-4338 michelle.ravert@alcon.com
Secondary Correspondent	Adrian Waechter Team Manager Regulatory Affairs WaveLight GmbH, on behalf of Alcon Laboratories, Inc. Am Wolfsmantel 5, 91058 Erlangen, Germany +49 9131 6186 2121 adrian.waechter@alcon.com
Date Prepared	December 19, 2025

Cylite Pty Ltd.
UNITY™ DX Device
510(k) Summary

2. SUBJECT DEVICE [per 807.92(a)(2)]

Device Trade Name:	UNITY™ DX
Regulation Numbers:	21 CFR 886.1570
Regulation Description:	Ophthalmoscope
Device Common Name:	Optical Coherence Tomography
Device Class:	II
Classification Panel:	Ophthalmic
Classification Product	OBO
Code: Subsequent Product	HJO

3. PREDICATE AND REFERENCE DEVICE [per 807.92(a)(3)]

Predicate Device 1:

Company Name:	Cylite Pty. Ltd.
Device Trade Name:	HP-OCT™ (K231760)
Regulation Number:	21 CFR 886.1570
Regulation Description:	Ophthalmoscope
Device Common Name:	Optical Coherence Tomography
Device Class:	II
Classification Panel:	Ophthalmic
Classification Product Code:	OBO
Subsequent Product Codes:	MXK, HJO

Predicate Device 2

Company Name	Carl Zeiss Meditec AG (K173771)
Device Trade Name:	IOL Master 700
Regulation Number:	21 CFR 886.1850
Regulation Description:	AC-powered slit lamp biomicroscope
Device Common Name:	Biometer
Device Class:	II
Classification Panel:	Ophthalmic
Classification Product Code:	HJO

Reference Device

Company Name	Santec Corporation
Device Trade Name:	Argos
Regulation Number:	21 CFR 886.1850
Regulation Description:	AC-powered slit lamp biomicroscope
Device Common Name:	Optical Biometer
Device Class:	II
Classification Panel:	Ophthalmic
Classification Product Code:	MXK, HJO

The subject device, predicate devices, and reference device are intended for non-contact imaging and analysis of ocular structures. The additional indications for use (IFU) offered by the predicate device do not change the intended use.

4. DEVICE DESCRIPTION [per 807.92(a)(4)]

The UNITY DX instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of anterior and posterior ocular structures and measurement of anterior segment and biometric parameters including axial length, anterior chamber depth, corneal thickness, lens thickness, and reference image. The UNITY DX device has four (4) measurement modalities: HP-OCT, wavefront measurement, reference image, and reflective topography.

5. INTENDED USE STATEMENT [per 807.92(a)(5)]

The UNITY DX instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of anterior and posterior ocular structures and measurement of anterior segment and biometric parameters including:

- Axial Length
- Anterior Chamber Depth
- Central Corneal Thickness
- Lens Thickness

The Reference Image functionality is intended for use as an ocular image capture tool.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS [per 807.92(a)(6)]

Reference **Table 1** for a summary of technical characteristics between the subject device, predicate devices, and reference device.

Table 1 – Summary of Technical Characteristics

Characteristics	Predicate Device 1 Cylite HP-OCT (K231760)	Predicate Device 2 Carl Zeiss IOLMaster 700 (K173771)	Reference Device Santec Corporation ARGOS (K191051)	Proposed Subject Device UNITY DX	SE Justification / Comment
Regulatory Characteristics	Regulatory Characteristics				
Manufacturer	Cylite Pty Ltd	Carl Zeiss Meditec AG	Santec Corporation	Cylite Pty Ltd	-
Model	HP-OCT	IOLMaster 700	ARGOS	UNITY DX	-
Class	II	Same	Same	Same	Same.
Classification Panel	Ophthalmic device panel	Same	Same	Same	Same.
Product Code	OBO	HJO	MXK, HJO	OBO; HJO	Substantially equivalent.
Regulation	21 CFR 886.1570	21 CFR 886.1850	21 CFR 886.1850	21 CFR 886.1570 21 CFR 886.1850	Substantially equivalent.
Common Name	Optical Coherence Tomography	Biometer	Optical Biometer	Same as predicate device 1.	Substantially equivalent.
Clinical Characteristics	Clinical Characteristics				
Intended Use	Non-contact imaging and analysis of ocular structures	Same	Same	Same	Same.
Indications for Use	The HP-OCT™ instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of the posterior segment of the eye.	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	ARGOS is a non-invasive, non-contact biometer based on swept-source optical coherence tomography (SS-OCT). The device is intended to acquire ocular measurements as well as perform calculations to determine the appropriate intraocular lens (IOL) power and type for implantation during intraocular lens placement. ARGOS	The UNITY DX instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of anterior and posterior ocular structures and measurement of anterior segment and biometric parameters including: • Axial Length • Anterior Chamber Depth • Central Corneal Thickness • Lens Thickness	Substantially equivalent.

Cylite Pty Ltd.
 UNITY™ DX Device
 510(k) Summary

Characteristics	Predicate Device 1 Cylite HP-OCT (K231760)	Predicate Device 2 Carl Zeiss IOLMaster 700 (K173771)	Reference Device Santec Corporation ARGOS (K191051)	Proposed Subject Device UNITY DX	SE Justification / Comment
		• Axial length • Anterior chamber depth • Pupil diameter • White-to-white distance (WTW)	measures the following 9 parameters: Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K-values (Radii of flattest and steepest meridians), Astigmatism, White-to-white (corneal diameter) and Pupil Size. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool. It is intended for use by ophthalmologists, physicians, and other eye-care professionals and may only be used under the supervision of a physician.	The Reference Image functionality is intended for use as an ocular image capture tool.	
Intended Users	Ophthalmologists Optometrists Other clinicians.	Same	Same	Same	Same.
Environment of Use	Ophthalmic clinics and hospitals.	Same	Same	Same	Same.
Measured Parameters	N/A	• Anterior chamber depth • Axial length • Corneal curvature • Corneal thickness • Lens thickness	• Axial Length • Corneal Thickness • Anterior Chamber Depth • Lens Thickness • K-values (Radii of flattest and steepest meridians) • Astigmatism	• Anterior chamber depth • Axial Length • Corneal Thickness • Lens Thickness	Same as predicate device 2.

Cylite Pty Ltd.
 UNITY™ DX Device
 510(k) Summary

Characteristics	Predicate Device 1 Cylite HP-OCT (K231760)	Predicate Device 2 Carl Zeiss IOLMaster 700 (K173771)	Reference Device Santec Corporation ARGOS (K191051)	Proposed Subject Device UNITY DX	SE Justification / Comment
			- White-to-white (corneal diameter) - Pupil Size		
Retinal Imaging	Yes	Yes (fovea only)	No	Same as predicate device 1.	Same as predicate device 1.
Reference Image					
Reference Image	No	Yes	Yes	Same as predicate 2 and reference device.	Substantially equivalent to predicate device 2 and reference device.
Reference Image – Light Source Illumination	N/A	Green LEDs	White light	Same as Reference Device	Substantially equivalent to predicate device 2 and equivalent to reference device for this characteristic. Bench testing did not raise different questions of safety or effectiveness.
Technical Characteristics					
Operating Principles	Hyperparallel OCT	Spectral domain interferometry	Swept-source optical coherence tomography (SS-OCT)	Same as Predicate 1.	Same as predicate device 1.
OCT Light Source	Superluminescent Diode, SLD (840 nm)	Swept source laser (1055nm)	Swept source laser (1060nm)	Same as Predicate 1.	Same as predicate device 1.
OCT Fixation/ Illumination Light Source	LED – White (6500 K), Red (633 nm), IR (940 nm)	LED – 660nm	Red (630nm) delivered power <10nW	OLED	Substantially equivalent.

Cylite Pty Ltd.
 UNITY™ DX Device
 510(k) Summary

Characteristics	Predicate Device 1 Cylite HP-OCT (K231760)	Predicate Device 2 Carl Zeiss IOLMaster 700 (K173771)	Reference Device Santec Corporation ARGOS (K191051)	Proposed Subject Device UNITY DX	SE Justification / Comment
OCT Acquisition Rate	>300K A-scans/second	2000 A-scans/second ¹	3000 A-scans/second ²	Equivalent to predicate device 1.	Substantially Equivalent.
OCT Axial resolution	9.0µm in tissue	22µm in tissue ³	50µm in water or vitreous humor ⁴	10.9µm in tissue	Substantially equivalent.
Lateral resolution	Retinal: 19µm	Anterior: Unknown.	100µm in water or vitreous humor ⁵	Retinal (Retinal Lens): Equivalent to Predicate device 1. Anterior (Topography Lens): 33µm	Substantially equivalent.
OCT measurements • Anterior Chamber Depth: • Axial Length: • Corneal thickness: • Lens thickness:	N/A N/A N/A N/A	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	Substantially equivalent.
Rated voltage / frequency	100 V to 240 V AC (± 10 %) / 50/60 Hz	Same	Same	Same	Same as predicate 1 and 2.
Power consumption	Max 120 VA	150 W	63 W	Same as predicate 1	Substantially equivalent.
Operating conditions	Temperature: 10°C to +35°C Relative humidity: 30% to 90%	Temperature: 10°C to +35°C, Relative humidity: 30% to 80% (noncondensing)	Temperature: 15°C to +35°C, Relative humidity: 30% to 70%	Same as predicate 1	Same as predicate 1.

¹ Source: Hirnschall, Nino, et al. (2018, Mar 01). Enhanced Penetration for Axial Length Measurement of Eyes with Dense Cataracts Using Swept Source Optical Coherence Tomography: A Consecutive Observational Study. <https://pmc.ncbi.nlm.nih.gov/articles/PMC5997603/>. doi: 10.1007/s40123-018-0122-1.

² Source: Orts-Vill, Paz, et al (2024, Sep 25). Axial length acquisition success rates and agreement of two swept-source optical biometers in eyes with dense cataracts. [https://pmc.ncbi.nlm.nih.gov/articles/PMC11461292/#:~:text=The%20Argos%20uses%20a%20wavelength,1.336;%20lens:%201.410\)](https://pmc.ncbi.nlm.nih.gov/articles/PMC11461292/#:~:text=The%20Argos%20uses%20a%20wavelength,1.336;%20lens:%201.410).). doi: 10.3389/fmed.2024.1449867.

³ Source: Hirnschall, Nino, et al. (2018, Mar 01). Enhanced Penetration for Axial Length Measurement of Eyes with Dense Cataracts Using Swept Source Optical Coherence Tomography: A Consecutive Observational Study. <https://pmc.ncbi.nlm.nih.gov/articles/PMC5997603/>. doi: 10.1007/s40123-018-0122-1.

⁴ Source: Argos User Manual

⁵ Source: Argos User Manual

Cylite Pty Ltd.
 UNITY™ DX Device
 510(k) Summary

Characteristics	Predicate Device 1 Cylite HP-OCT (K231760)	Predicate Device 2 Carl Zeiss IOLMaster 700 (K173771)	Reference Device Santec Corporation ARGOS (K191051)	Proposed Subject Device UNITY DX	SE Justification / Comment
Storage conditions	Temperature: 0°C to +45°C Relative Humidity: 10% to 95%	Temperature: -20°C to +60°C, Relative humidity: 10% to 90% (noncondensing)	Temperature: -10°C to +55°C, Relative humidity: 10% to 95%	Same as predicate 1	Same as predicate 1.
Transportation conditions	Temperature: 0°C to +45°C Relative Humidity: 10% to 95%	Temperature: -20°C to +60°C, Relative humidity: 10% to 90% (noncondensing)	Temperature: -40°C to +70°C, Relative humidity: 10% to 95%	Same as predicate 1	Same as predicate 1.
Biological Characteristics	Biological Characteristics				
Patient Contacting Parts	Chin and head rest	Same	Same	Same	Same as predicate 1.
Contacts body area	Chin and forehead	Same	Same	Same	Same as predicate 1.
Invasive	No	Same	Same	Same	Same.
Contacts intact skin only	Yes	Same	Same	Same	Same.
Surface Contacting Devices (ISO10993-1)	Yes	Same	Same	Same	Same.
Skin contact duration (typical)	< 24 hours	Same	Same	Same	Same.
Reusable	Yes	Same	Same	Same	Same.
Sterile	No	Same	Same	Same	Same.
Biocompatibility	ISO 10993-1/5/10	Same	Unknown	Same as predicate 1 and 2.	Same as predicate 1 and 2.

7. SUMMARY OF PERFORMANCE DATA [per 807.92(b)]

7.1. Non-Clinical Testing Summary [per 807.92(b)(1)]

Non-clinical performance tests have been conducted on the subject device, the UNITY™ DX instrument, to demonstrate the substantial equivalence to the predicate device, the HP-OCT instrument, including:

7.1.1. *Biocompatibility*

Biocompatibility of the device was previously demonstrated on the predicate device by cytotoxicity testing and skin sensitization testing according to ISO 10993-5:2009 and ISO 10993-10:202, respectively, and supported by biocompatibility assessment according to 10993-1:2018. The test results remain valid for the subject device.

Biocompatibility assessment was performed in accordance with the following international and consensus standards

- ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process.
- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2021 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

7.1.2. *Sterilization and Shelf Life*

The device is provided non-sterile. Sterilization and Shelf-Life data are not required to support substantial equivalence.

7.1.3. *Electromagnetic Compatibility (EMC)/ Wireless / Electrical Safety*

7.1.3.1. *Electrical, mechanical, and thermal Safety*

Electrical, mechanical and thermal safety tests were performed on the subject device in accordance with the following international and consensus standards and passed the relevant requirements of the applied standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.
- ANSI/AAMI ES60601-1:2005/(R)2012 - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.

7.1.3.2. *Electromagnetic compatibility*

Electromagnetic compatibility tests were performed on the subject device in accordance with the following consensus standard and passed the relevant requirements of the applied standard:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION - Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

7.1.4. Software and Cybersecurity

Software verification and validation tests were submitted as a “Basic Documentation Level” in accordance FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Device Software Functions”, issued June 14, 2023. The development of the software also complied with the consensus standard IEC 62304:2015 -Medical Device Software life-cycle processes.

Documentation regarding cybersecurity was submitted as recommended by FDA’s Guidance for Industry and FDA Staff, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”, issued June 27, 2025, and an overall risk assessment regarding security and safety of the device was conducted due to ISO 14971:2019.

7.1.5. Performance Testing

Bench verification testing was conducted to demonstrate optical Image performances including resolution, field of view, axial range, signal-to-noise ratio and depth attenuation and performance of auxiliary functions. The device met all pre-determined acceptance criteria.

7.1.5.1. Optical imaging performance

Bench verification testing was conducted to demonstrate optical Image performances including resolution, field of view, axial range, signal-to-noise ratio and depth attenuation. The device met all pre-determined acceptance criteria.

7.1.5.2. Optical Safety

Optical safety tests and assessments were performed for the light sources used in the subject device in accordance with the following international and consensus standards and passed the relevant requirements of the applied standards.

- ISO 15004-1:2020 - Ophthalmic instruments – Fundamental requirements and test methods– Part 1: General requirements applicable to all ophthalmic instruments.
- ISO 15004-2:2007 - Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection.
- ANSI Z80.36:2021 - American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.

The device met all pre-determined acceptance criteria.

7.1.6. Human Factors and Usability

Human factors validation (usability summative evaluation) in accordance with FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices” and the consensus standard IEC 62366-1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices.

7.1.7. Animal Testing

Animal testing was not required to support substantial equivalence.

7.2. Clinical Testing Summary [per 807.92(b)(2)]

A clinical study was conducted at a single site in the USA to validate the clinical performance of the UNITY DX device and demonstrate substantial equivalence to the predicate device, the IOLMaster 700. This study compared the agreement, repeatability, and reproducibility for biometric measurements taken by UNITY DX to those taken by IOLMaster 700, using a crossed design wherein each subject eye was measured by 3 operators on 3 paired configurations of UNITY DX and IOLMaster 700, respectively. Biometric parameters, namely Central Corneal Thickness [CCT] (μm), Lens Thickness [LT] (mm), Anterior Chamber Depth [ACD] (mm), and Axial Length [AL] (mm), were investigated for agreement (Bland-Altman and Deming regression) and precision [repeatability and reproducibility].

A total of 176 subjects, 22 years or older, were screened and recruited for the following cohorts:

- Group 1: normal subjects
- Group 2: cataract subjects
- Group 3: subjects with significant refractive errors (myopia $\geq -6\text{D}$ and/or hyperopia $\geq +5\text{D}$)
- Group 4: subjects with abnormal corneal topography

Of the 159 subjects who completed the study, the average age was 45.8 ± 16.68 years old (Group 1: 30.2 ± 6.27 ; Group 2: 64.7 ± 9.02 ; Group 3: 40.6 ± 11.32 ; Group 4: 45.2 ± 15.18) and 59.7% were female.

Of the study population, 72.3% identified as white, 18.9% as Asian, 13.2% as Hispanic or Latino, 7.5% as Black or African American, 0.6% as American Indian or Alaska Native, and 0.6% as Unknown.

Study results showed that measurements from UNITY DX showed good agreement, and were comparable to IOLMaster 700 measurements for all parameters (**Table 3** and **Table 4**). The 95% confidence intervals (CIs) on the Bland-Altman Limits of Agreement (LoA) were contained within the relevant clinically-acceptable error that was pre-specified for each parameter.

The measurement range for the different parameters on UNITY DX are outlined in the table below.

Table 2. UNITY DX Clinical Targets

Parameter	Clinical Acceptance Bounds	Measurement Range
Anterior Chamber Depth	-0.769 mm to 0.769 mm	1.75 mm to 6.5 mm
Axial Length	-0.192 mm to 0.192 mm	14 mm to 35 mm
Central Corneal thickness	-333 μm to 333 μm	150 μm to 1500 μm
Lens thickness	-1.33 mm to 1.33 mm	0.5 mm to 6.0 mm

Repeatability and reproducibility were comparable between devices across all studied population groups, and consistently comparable, or lower, standard deviations and relative standard deviations were observed in UNITY DX (**Table 5** and **Table 6**).

To aid user clinical judgement, the UNITY DX device flags the following as an unacceptable scan in the post-analysis summary screen: poor quality based on measurement data repeatability, no measurement value obtained, or operator detection of incorrect segmentation (i.e., Corneal/lens/RPE segmentation error). In the clinical study, the number of subjects with at least 3 acceptable scans (one

for each operator) on UNITY DX was observed to be 96.2%. Therefore, the unacceptable rate of subjects not included in the agreement analysis was 3.8%.

The secondary performance endpoint was the comparison of the Sum-of-Segment (SoS)-based AL (AL-SoS) and ACD (ACD-SoS) measurements by UNITY DX to the regression-based measurement of IOLMaster 700. A proportional agreement between UNITY DX and IOLMaster 700 was observed with a fixed offset between ACD-SoS/AL-SoS measured by UNITY DX and ACD/AL measured by IOLMaster 700. The differences between the Sum of Segments measurements (AL-SoS and ACD-SoS) from UNITY DX and the AL/ACD measurements from IOLMaster 700 were expected due to the difference in the method used to calculate physical distance from optical path length, which resulted in shorter measurements in longer eyes and longer measurement values in short eyes when compared to regression-based methods. The repeatability and reproducibility SoS-derived measurements were comparable between devices across all population groups studied, and consistently comparable, or lower, standard deviations and relative standard deviations were observed in UNITY DX (**Table 7** and **Table 8**).

There were no adverse events (AEs) or adverse device effects (ADEs) reported during this study from informed consent through study exit.

Table 3. Bland-Altman Limits of Agreement and 95% Confidence Intervals by Population Group and Parameter – Agreement Analysis Set

Study Population Parameter	N	Number of Scans		95% LoA	95% CI around LoA [1]	Clinically Acceptable Bounds
		UNITY DX	IOLMaster 700			
		n	n			
Normal Eyes (Group 1)						
CCT (μm)	36	108	108	(-13.3217, 4.2795)	(-15.1568, 6.1146)	(-333, 333)
ACD (mm)	36	108	108	(-0.0476, 0.0436)	(-0.0580, 0.0541)	(-0.769, 0.769)
AL (mm)	36	108	108	(-0.0803, 0.0511)	(-0.0943, 0.0650)	(-0.192, 0.192))
LT (mm)	36	108	108	(-0.0571, 0.0632)	(-0.0706, 0.0767)	(-1.33, 1.33)
Cataracts (Group 2)						
CCT (μm)	43	124	129	(-17.0853, 6.1423)	(-19.4184, 8.4754)	(-333, 333)
ACD (mm)	43	124	129	(-0.0474, 0.0140)	(-0.0534, 0.0200)	(-0.769, 0.769)
AL (mm)	43	124	129	(-0.0496, 0.0262)	(-0.0571, 0.0338)	(-0.192, 0.192))
LT (mm)	43	124	129	(-0.2336, 0.2531)	(-0.2807, 0.3002)	(-1.33, 1.33)
Significant Refractive Error (Group 3)						
CCT (μm)	41	122	122	(-14.5245, 5.7227)	(-16.5156, 7.7139)	(-333, 333)
ACD (mm)	41	122	122	(-0.0651, 0.0461)	(-0.0767, 0.0577)	(-0.769, 0.769)
AL (mm)	41	122	122	(-0.1111, 0.0915)	(-0.1318, 0.1122)	(-0.192, 0.192))
LT (mm)	41	122	122	(-0.0597, 0.0865)	(-0.0747, 0.1014)	(-1.33, 1.33)

Abnormal Corneal Topography (Group 4)

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Study Population Parameter	N	Number of Scans		95% LoA	95% CI around LoA [1]	Clinically Acceptable Bounds
		UNITY DX n	IOLMaster 700 n			
CCT (µm)	37	111	111	(-15.0167, 10.0576)	(-17.7763, 12.8172)	(-333, 333)
ACD (mm)	37	111	111	(-0.0601, 0.0498)	(-0.0717, 0.0613)	(-0.769, 0.769)
AL (mm)	37	111	111	(-0.0444, 0.0241)	(-0.0514, 0.0311)	(-0.192, 0.192))
LT (mm)	37	111	111	(-0.0851, 0.1099)	(-0.1052, 0.1299)	(-1.33, 1.33)

Abbreviations: CI = Confidence Interval; LoA = Limits of Agreement; µm = Micrometers; mm = Millimeters.

Note: The Bland-Altman analysis was conducted utilizing the first acceptable scan per operator-device configuration. Bland-Altman limits of agreement using repeated measurements with unequal numbers of replicates was applied. The confidence interval was calculated using the method of Bland and Altman (1999).

[1] Lower CI for the lower LOA and the upper CI for the upper LOA.

Table 4. Table 4. Deming Regression Slope and Intercept by Population Group and Parameter – Agreement Analysis Set

Study Population Parameter	N	Number of Scan Pairs (UNITY DX, IOLMaster 700)	Slope (95% CI)	Intercept (95% CI)
Normal Eyes (Group 1)				
CCT (μm)	36	108	0.965 (0.9518, 0.9775)	14.718 (7.5202, 21.9160)
ACD (mm)	36	108	0.981 (0.9533, 1.0094)	0.064 (-0.0366, 0.1643)
AL (mm)	36	108	0.992 (0.9759, 1.0074)	0.186 (-0.1863, 0.5576)
LT (mm)	36	108	0.945 (0.9156, 0.9748)	0.209 (0.0979, 0.3211)
Cataracts (Group 2)				
CCT (μm)	43	124	0.972 (0.9232, 1.0208)	10.121 (-17.3760, 37.6182)
ACD (mm)	43	124	0.988 (0.9792, 0.9977)	0.021 (-0.0086, 0.0510)
AL (mm)	43	124	1.000 (0.9961, 1.0030)	-0.001 (-0.0835, 0.0812)
LT (mm)	43	124	0.988 (0.9332, 1.0435)	0.063 (-0.1775, 0.3034)
Significant Refractive Error (Group 3)				
CCT (μm)	41	121	0.969 (0.9388, 1.0000)	12.053 (-4.5977, 28.7036)
ACD (mm)	41	121	0.985 (0.9611, 1.0081)	0.047 (-0.0402, 0.1337)
AL (mm)	41	121	1.002 (0.9870, 1.0162)	-0.052 (-0.4284, 0.3242)
LT (mm)	41	121	0.991 (0.9732, 1.0085)	0.050 (-0.0206, 0.1198)
Abnormal Corneal Topography (Group 4)				
CCT (μm)	37	111	0.971 (0.9436, 0.9992)	12.053 (-1.5093, 25.6146)

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Study Population Parameter	N	Number of Scan Pairs (UNITY DX, IOLMaster 700)	Slope (95% CI)	Intercept (95% CI)
ACD (mm)	37	111	0.999 (0.9815, 1.0163)	-0.001 (-0.0617, 0.0588)
AL (mm)	37	111	0.998 (0.9953, 1.0015)	0.030 (-0.0483, 0.1073)
LT (mm)	37	111	1.000 (0.9819, 1.0181)	0.012 (-0.0586, 0.0832)

Abbreviations: CI = Confidence Interval; μm = Micrometers; mm = Millimeters.

Note: The Deming regression analysis was conducted utilizing the first acceptable scan per operator-device configuration. Regression Intercept and Slope were calculated with a Deming regression model using the leave-one-subject jackknife procedure to estimate standard errors. The confidence interval was calculated using the method of Linnet (1990).

Table 5. Repeatability and Reproducibility of UNITY DX® Biometry Measurements – Precision Analysis Set

Study Population Parameter	n	Intercept	Repeatability			Reproducibility		
			SD	Limit	CV%	SD	Limit	CV%
Normal Eyes (Group 1)								
CCT (μm)	31	540.104	0.941	2.634	0.174%	1.435	4.018	0.266%
ACD (mm)	31	3.526	0.006	0.018	0.183%	0.009	0.025	0.258%
AL (mm)	31	23.981	0.004	0.012	0.017%	0.006	0.015	0.023%
LT (mm)	31	3.776	0.008	0.022	0.210%	0.009	0.026	0.242%
Cataracts (Group 2)								
CCT (μm)	34	545.593	1.076	3.014	0.197%	1.531	4.288	0.281%
ACD (mm)	34	3.245	0.005	0.015	0.161%	0.009	0.024	0.267%
AL (mm)	34	24.031	0.005	0.014	0.021%	0.007	0.018	0.027%
LT (mm)	34	4.532	0.054	0.151	1.188%	0.082	0.229	1.808%
Significant Refractive Error (Group 3)								
CCT (μm)	37	531.020	1.278	3.577	0.241%	2.011	5.632	0.379%
ACD (mm)	37	3.646	0.011	0.032	0.314%	0.014	0.040	0.390%

Study Population Parameter	n	Repeatability				Reproducibility		
		Intercept	SD	Limit	CV%	SD	Limit	CV%
AL (mm)	37	26.463	0.006	0.016	0.021%	0.007	0.019	0.026%
LT (mm)	37	3.974	0.020	0.057	0.514%	0.022	0.062	0.554%
Abnormal Corneal Topography (Group 4)								
CCT (µm)	33	507.246	1.016	2.844	0.200%	1.653	4.629	0.326%
ACD (mm)	33	3.490	0.011	0.031	0.322%	0.015	0.043	0.443%
AL (mm)	33	24.565	0.004	0.012	0.018%	0.006	0.016	0.023%
LT (mm)	33	4.028	0.022	0.063	0.557%	0.025	0.070	0.619%

Abbreviations: CV = Coefficient of Variation; µm = Micrometers; mm = Millimeters; SD = Standard Deviation.

Note: The Precision Analysis Set used subjects with 9 acceptable scans per device type (3 replicates each from 3 operator/device configurations – the operator and device are confounded); n represents the number of subjects with available data. The crossed two-way random-effects analysis of variance (ANOVA) model included configuration, subject, and configuration x subject interaction; the restricted maximum likelihood method (REML) was used for estimation. Repeatability SD = square root of the residual variance; Repeatability limit = 2.8 x Repeatability SD; Repeatability CV% = (Repeatability SD / mean) x 100%. Reproducibility SD = square root of the sum of the configuration variance, the interaction variance, and the residual variance; Reproducibility limit = 2.8 x Reproducibility SD; Reproducibility CV% = (Reproducibility SD / mean) x 100%.

Table 6. Repeatability and Reproducibility of IOLMaster 700 Biometry Measurements – Precision Analysis Set

Study Population Parameter	n	Intercept	Repeatability			Reproducibility		
			SD	Limit	CV%	SD	Limit	CV%
Normal Eyes (Group 1)								
CCT (μm)	31	544.273	2.286	6.401	0.420%	4.404	12.331	0.809%
ACD (mm)	31	3.529	0.009	0.025	0.258%	0.014	0.040	0.404%
AL (mm)	31	23.994	0.017	0.048	0.071%	0.031	0.086	0.129%
LT (mm)	31	3.771	0.011	0.032	0.303%	0.023	0.063	0.597%
Cataracts (Group 2)								
CCT (μm)	34	551.185	2.404	6.730	0.436%	4.588	12.846	0.832%
ACD (mm)	34	3.259	0.007	0.020	0.221%	0.011	0.030	0.333%
AL (mm)	34	24.043	0.005	0.014	0.021%	0.015	0.042	0.063%
LT (mm)	34	4.522	0.034	0.094	0.745%	0.059	0.166	1.311%
Significant Refractive Error (Group 3)								
CCT (μm)	37	534.979	2.125	5.950	0.397%	3.906	10.936	0.730%
ACD (mm)	37	3.656	0.012	0.035	0.338%	0.020	0.056	0.547%

Study Population Parameter	n	Intercept	Repeatability			Reproducibility		
			SD	Limit	CV%	SD	Limit	CV%
AL (mm)	37	26.471	0.015	0.041	0.055%	0.042	0.118	0.159%
LT (mm)	37	3.959	0.014	0.039	0.354%	0.023	0.066	0.593%
Abnormal Corneal Topography (Group 4)								
CCT (µm)	33	509.185	2.051	5.744	0.403%	4.787	13.404	0.940%
ACD (mm)	33	3.497	0.010	0.028	0.285%	0.015	0.043	0.435%
AL (mm)	33	24.574	0.004	0.012	0.017%	0.016	0.045	0.066%
LT (mm)	33	4.013	0.023	0.065	0.581%	0.039	0.108	0.965%

Abbreviations: CV = Coefficient of Variation; µm = Micrometers; mm = Millimeters; SD = Standard Deviation.

Note: The Precision Analysis Set used subjects with 9 acceptable scans per device type (3 replicates each from 3 operator/device configurations – the operator and device are confounded); n represents the number of subjects with available data. The crossed two-way random-effects analysis of variance (ANOVA) model included configuration, subject, and configuration x subject interaction; the restricted maximum likelihood method (REML) was used for estimation. Repeatability SD = square root of the residual variance; Repeatability limit = 2.8 x Repeatability SD; Repeatability CV% = (Repeatability SD / mean) x 100%. Reproducibility SD = square root of the sum of the configuration variance, the interaction variance, and the residual variance; Reproducibility limit = 2.8 x Reproducibility SD; Reproducibility CV% = (Reproducibility SD / mean) x 100%.

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 Table 7. Repeatability and Reproducibility – Precision Analysis Set – AL-SoS

			Repeatability			Reproducibility		
Device								
Study Population	n	Intercept	SD	Limit	CV%	SD	Limit	CV%
UNITY DX®								
Normal Eyes (Group 1)	31	24.010	0.004	0.011	0.016%	0.005	0.015	0.022%
Cataracts (Group 2)	34	24.010	0.006	0.016	0.023%	0.007	0.020	0.030%
Significant Refractive Error (Group 3)	37	26.380	0.006	0.016	0.021%	0.007	0.019	0.025%
Abnormal Corneal Topography (Group 4)	33	24.556	0.004	0.012	0.017%	0.005	0.015	0.021%
IOLMaster 700								
Normal Eyes (Group 1)	31	23.994	0.017	0.048	0.071%	0.031	0.086	0.129%
Cataracts (Group 2)	34	24.043	0.005	0.014	0.021%	0.015	0.042	0.063%
Significant Refractive Error (Group 3)	37	26.471	0.015	0.041	0.055%	0.042	0.118	0.159%
Abnormal Corneal Topography (Group 4)	33	24.574	0.004	0.012	0.017%	0.016	0.045	0.066%

Abbreviations: CV = Coefficient of Variation; µm = Micrometers; mm = Millimeters; SD = Standard Deviation.

Note: The Precision Analysis Set used subjects with 9 acceptable scans per device type (3 replicates each from 3 operator/device configurations – the operator and device are confounded); n represents the number of subjects with available data. The crossed two-way random-effects analysis of variance (ANOVA) model included configuration, subject, and configuration x subject interaction; the restricted maximum likelihood method (REML) was used for estimation. Repeatability SD = square root of the residual variance; Repeatability limit = 2.8 x Repeatability SD; Repeatability CV% = (Repeatability SD / mean) x 100%. Reproducibility SD = square root of the sum of the configuration variance, the interaction variance, and the residual variance; Reproducibility limit = 2.8 x Reproducibility SD; Reproducibility CV% = (Reproducibility SD / mean) x 100%.

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 Table 8. Repeatability and Reproducibility – Precision Analysis Set – ACD-SoS

			Repeatability			Reproducibility		
Device								
Study Population	n	Intercept	SD	Limit	CV%	SD	Limit	CV%
UNITY DX®								
Normal Eyes (Group 1)	31	3.626	0.006	0.018	0.178%	0.009	0.025	0.251%
Cataracts (Group 2)	34	3.345	0.005	0.015	0.156%	0.009	0.024	0.259%
Significant Refractive Error (Group 3)	37	3.746	0.011	0.032	0.306%	0.014	0.040	0.379%
Abnormal Corneal Topography (Group 4)	33	3.590	0.011	0.031	0.313%	0.015	0.043	0.430%
IOLMaster 700								
Normal Eyes (Group 1)	31	3.529	0.009	0.025	0.258%	0.014	0.040	0.404%
Cataracts (Group 2)	34	3.259	0.007	0.020	0.221%	0.011	0.030	0.333%
Significant Refractive Error (Group 3)	37	3.656	0.012	0.035	0.338%	0.020	0.056	0.547%
Abnormal Corneal Topography (Group 4)	33	3.497	0.010	0.028	0.285%	0.015	0.043	0.435%

Abbreviations: CV = Coefficient of Variation; µm = Micrometers; mm = Millimeters; SD = Standard Deviation.

Note: The Precision Analysis Set used subjects with 9 acceptable scans per device type (3 replicates each from 3 operator/device configurations – the operator and device are confounded); n represents the number of subjects with available data. The crossed two-way random-effects analysis of variance (ANOVA) model included configuration, subject, and configuration x subject interaction; the restricted maximum likelihood method (REML) was used for estimation. Repeatability SD = square root of the residual variance; Repeatability limit = 2.8 x Repeatability SD; Repeatability CV% = (Repeatability SD / mean) x 100%. Reproducibility SD = square root of the sum of the configuration variance, the interaction variance, and the residual variance; Reproducibility limit = 2.8 x Reproducibility SD; Reproducibility CV% = (Reproducibility SD / mean) x 100%.

8. Conclusion [per 807.92(b)(3)]

The subject device, the UNITY™ DX Instrument, has the same intended use and the same data acquisition modes used by the legally marketed HP-OCT instrument (K231760) predicate device and Carl Zeiss IOL Master 700 secondary predicate device identified in this premarket notification. The technological characteristics of the subject UNITY DX instrument differ from those of the predicate and reference devices; however, the differences do not raise new or different questions of safety or effectiveness. Results of the non-clinical performance testing demonstrate that the UNITY DX instrument functions as intended. Results of the clinical performance testing illustrate that UNITY DX's ability to measure parameters of axial length, anterior chamber depth, central corneal thickness, and lens thickness is comparable to Carl Zeiss IOL Master 700 (K173771).

The statistical differences observed in various measurements do not have significant clinical impact. The study results support substantial equivalence of UNITY™ DX and the IOL Master 700 in regard to parameter measurements for axial length, anterior chamber depth, central corneal thickness, and lens thickness. The non-clinical and clinical performance testing demonstrate that the device is as safe, as effective, and performs as well or better than the legally marketed predicate devices and reference devices.

Therefore, comparison of intended use and technological characteristics and evaluation of non-clinical testing and clinical performance data support the substantial equivalence of the UNITY™ DX subject device to the predicate devices (Cylite's HP-OCT Instrument and Carl Zeiss' IOLMaster) and reference device (Santec's ARGOS device) for the indications for use.