FDA 510(k) Premarket Notification

K252633 UNITY DX (UDX)

CLEARED

Dec 23, 2025
125 days to decision

K252633 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k252633/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Aug 20, 2025
Decision date	Dec 23, 2025
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cylite Pty. , Ltd.**
Location	Mulgrave, AU
Contact	Arnold Ouyang
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Alcon Research, LLC**
Contact	Michelle Ravert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT06826599

Agreement and Precision Study of UNITY® DX and a Comparator Biometer

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	160 patients (actual)
Study sites	1 site
Condition studied	Normal Eyes; Abnormal Eyes
Study type	Observational
Completion date	Mar 30, 2025
Sponsor	Cylite Pty Ltd (Industry)

Primary outcome

Central corneal thickness (CCT)

Secondary outcome

Anterior Chamber Depth Sum of Segments (ACD-SoS)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06826599