FDA 510(k) Premarket Notification

K250553 Tomey Cornea/Anterior Segment OCT (CASIA2)

CLEARED

Jul 18, 2025
143 days to decision

K250553 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k250553/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Feb 25, 2025
Decision date	Jul 18, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tomey Corporation**
Location	Tokyo, JP
Contact	Yuko Matsushita
510(k) history	5 submissions · 5 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	**Ora, Inc.**
Contact	Roger Albright

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

CLINICAL EVIDENCE - NCT06065072

Comparative Study of the Tomey OA-2000, Tomey CASIA2, and the LenStar LS900

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	167 patients (estimated)
Study sites	1 site
Condition studied	Cataract; Aphakic Eye; Pseudophakia
Study type	Observational
Completion date	Oct 31, 2023
Sponsor	Tomey Corporation (Industry)

Primary outcome

Agreement between the test devices and predicate device

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06065072