K213265 Tomey Cornea/Anterior Segment OCT CASIA2

CLEARED

Apr 27, 2022
209 days to decision

K213265 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k213265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Sep 30, 2021
Decision date	Apr 27, 2022
Days to decision	209 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 - NCT04486976

Comparative Study of the Cornea/Anterior Segment OCT CASIA2 and the RTVue XR OCT Avanti With AngioVue Software

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	134 patients (actual)
Study sites	1 site
Condition studied	Glaucoma; Cataract
Primary purpose	Diagnostic
Study type	Interventional
Study design	Crossover
Masking	Open label
Completion date	Mar 5, 2021
Sponsor	Tomey Corporation (Industry)

Primary outcome

Agreement of Corneal thickness (?m) measurement for Cornea/Anterior Segment OCT CASIA2 and Optovue RTVue XR Avanti OCT

Secondary outcome

Adverse Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04486976