FDA 510(k) Premarket Notification

CLEARED

K252348 Tomey Optical Biometer OA-2000 (OA-2000)

Dec 18, 2025
142 days to decision

K252348 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k252348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Jul 29, 2025
Decision date	Dec 18, 2025
Days to decision	142 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, LLC**
Contact	Roger Albright

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