

K252348 Tomey Optical Biometer OA-2000 (OA-2000)Dec 18, 2025
142 days to decisionK252348 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252348/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026