

**K231222 3D OPTICAL COHERENCE TOMOGRAPHY 3D  
OCT-1(type: Maestro2)**Oct 30, 2023  
185 days to decisionK231222 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k231222/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Apr 28, 2023
Decision date	Oct 30, 2023
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Topcon Corporation</b>
Location	North Reading, MA, US
Contact	Ryota Kitawaki
Website	<a href="http://www.topcon.com">http://www.topcon.com</a>
510(k) history	13 submissions · 13 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231222/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026