

**K121622 NIDEK RS-3000**Mar 14, 2013  
286 days to decisionK121622 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k121622/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jun 1, 2012
Decision date	Mar 14, 2013
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nidek Co., Ltd.</b>
Location	Lake Forest, CA, US
Contact	LENA SATTLER
510(k) history	20 submissions · 19 cleared · 2001-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121622/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026