FDA 510(k) Premarket Notification

# K222166 SOLIX

**CLEARED**

Nov 9, 2022
111 days to decision

K222166 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k222166/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tomography, Optical Coherence (OBO) |
| Date received | Jul 21, 2022 |
| Decision date | Nov 9, 2022 |
| Days to decision | 111 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Optovue, Inc.** |
| Location | Fremont, CA, US |
| Contact | Robert Lundberg |
| 510(k) history | 16 submissions · 16 cleared · 2006-2022 |

## CLINICAL EVIDENCE - NCT03852485

### Comparison of OCT and OCTA-based Ocular Measurements to Those of Predicate

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|---|---|
| Status | Completed - *No results published to ClinicalTrials.gov* |
| Enrollment | 199 patients (actual) |
| Study sites | 2 sites |
| Condition studied | Normal Eyes and Eyes With Ocular Pathologies |
| Study type | Observational |
| Completion date | Aug 30, 2019 |
| Sponsor | Optovue (Industry) |

**Primary outcome**

Limits of agreement

**Secondary outcome**

Regression Analysis

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03852485