

K091404 IVUE, MODEL 100Apr 22, 2010
345 days to decisionK091404 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k091404/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tomography, Optical Coherence (OBO) |
| Date received | May 12, 2009 |
| Decision date | Apr 22, 2010 |
| Days to decision | 345 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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