

K221601 MS-39Sep 1, 2023
456 days to decisionK221601 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k221601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jun 2, 2022
Decision date	Sep 1, 2023
Days to decision	456 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	C.S.O. S.R.L.
Location	Williamsville, NY, US
Contact	Gilda Mura
510(k) history	3 submissions · 3 cleared · 2002-2023

REGULATORY CONSULTANT

Consulting firm	THEMA S.r.l.
Contact	Marisa Testa

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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