FDA 510(k) Premarket Notification

K221601 MS-39

CLEARED

Sep 1, 2023
456 days to decision

K221601 · 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