

K251320 XTRA4Sep 11, 2025
135 days to decisionK251320 · Product code: **LYX** · Ophthalmic
Source: <https://www.510kdatabase.net/k251320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Corneal Storage (LYX)
Date received	Apr 29, 2025
Decision date	Sep 11, 2025
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Al.Chi.Mi.A. S.R.L
Location	Ponte San Nicolo, IT
Contact	Niccolò Bufo
510(k) history	3 submissions · 2 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Allied Regulatory Consulting
Contact	Sean Griffin

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

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