FDA 510(k) Premarket Notification

# K251320 XTRA4

**CLEARED**

Sep 11, 2025
135 days to decision

K251320 · 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