

K221759 CornisolOct 5, 2022
110 days to decisionK221759 · Product code: **LYX** · Ophthalmic
Source: <https://www.510kdatabase.net/k221759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Corneal Storage (LYX)
Date received	Jun 17, 2022
Decision date	Oct 5, 2022
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aurolab
Location	Madison, WI, US
Contact	Krishna Kumar
510(k) history	4 submissions · 4 cleared · 2003-2022

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](https://accessdata.fda.gov)

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