FDA 510(k) Premarket Notification

K221759 Cornisol

CLEARED

Oct 5, 2022
110 days to decision

K221759 · 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