FDA 510(k) Premarket Notification

K222500 AIR OPTIX COLORS

CLEARED

Sep 15, 2022
28 days to decision

K222500 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k222500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Aug 18, 2022
Decision date	Sep 15, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alcon Laboratories, Inc.**
Location	Fort Worth, TX, US
Contact	Sherri Lakota
Website	https://www.alcon.com
510(k) history	43 submissions · 42 cleared · 1996-2026

Alcon Laboratories, Inc. is an eye care company headquartered in Fort Worth, Texas. The company develops innovative vision products and treatments for patients worldwide. Alcon maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions. The company specializes exclusively in Ophthalmic devices, a focus reflected across its entire submission portfolio. Alcon's regulatory activity spans from 1996 to 2026, with recent clearances demonstrating continued innovation in vision care technologies. Recent FDA 510(k) clearances include con...

REGULATORY CONSULTANT

Consulting firm	**Alcon / Ciba Vision GmbH**
Contact	Dr.Andreas Friese

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