FDA 510(k) Premarket Notification

K230785 Precision1, Precision1 for Astigmatism

CLEARED

Apr 20, 2023
29 days to decision

K230785 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k230785/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Mar 22, 2023
Decision date	Apr 20, 2023
Days to decision	29 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	Andreas Friese

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

CLINICAL EVIDENCE - NCT03305770

DD T2 Daily Disposable Registration Trial

Status	Completed
Enrollment	107 patients (actual)
Study sites	6 sites
Condition studied	Myopia; Refractive Errors
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Feb 21, 2018
Sponsor	Alcon Research (Industry)

Primary outcome

Monocular Visual Acuity (VA) With Contact Lenses at Each Visit (Snellen)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03305770