FDA 510(k) Premarket Notification

K243909 Precision1

CLEARED

Jan 13, 2025
25 days to decision

K243909 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k243909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Dec 19, 2024
Decision date	Jan 13, 2025
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Precision1 for Astigmatism; Dailies Total1; Dailies Total1 for Astigmatism; Dailies Total1 Multifocal; Dailies Total1 Multifocal Toric

APPLICANT

Company	**Alcon Laboratories, Inc.**
Location	Fort Worth, TX, US
Contact	Andreas Friese
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...