

K233856 Precision1Dec 29, 2023
24 days to decisionK233856 · Product code: **LPL** · Ophthalmic
Source: <https://www.510kdatabase.net/k233856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Dec 5, 2023
Decision date	Dec 29, 2023
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Precision1 for Astigmatism; TOTAL30; TOTAL30 for Astigmatism; TOTAL30 Multifocal

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

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Device record: <https://www.510kdatabase.net/k233856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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