FDA 510(k) Premarket Notification

K212806 Alcon (serafilcon A) soft contact lenses for daily wear

CLEARED

Dec 28, 2021
116 days to decision

K212806 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k212806/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Sep 3, 2021
Decision date	Dec 28, 2021
Days to decision	116 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	Alicia Plesnarski
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...

CLINICAL EVIDENCE - NCT03920280

Clinical Evaluation of a Daily Wear Frequent Replacement Silicone Hydrogel Lens

Status	Completed
Enrollment	120 patients (actual)
Study sites	8 sites
Condition studied	Refractive Errors
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Oct 5, 2019
Sponsor	Alcon Research (Industry)

Primary outcome

Distance Visual Acuity (VA) With Study Lenses - Completed Eyes

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03920280