

K230954 Samfilcon B Custom Contact LensNov 17, 2023
227 days to decisionK230954 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k230954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 4, 2023
Decision date	Nov 17, 2023
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bausch & Lomb, Incorporated
Location	Rochester, NY, US
Contact	Barbara Klube-Falso
510(k) history	27 submissions · 27 cleared · 2002-2024

CLINICAL EVIDENCE - NCT03897712**A Study to Evaluate the Safety and Effectiveness of a Silicone Hydrogel Custom Contact Lens When Compared to Alden Optical HP Sphere Lenses**

Status	Completed
Enrollment	84 patients (actual)
Study sites	7 sites
Condition studied	Contact Lens Wear
Primary purpose	Supportive_care
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Aug 28, 2019
Sponsor	Bausch & Lomb Incorporated (Industry)

Primary outcome

Mean Distance High-contrast logMAR Lens VA

Secondary outcome

Proportion Of Eyes With Grade >2 Slit Lamp Findings

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03897712