FDA 510(k) Premarket Notification

CLEARED

K200528 Bausch + Lomb (Kalifilcon A) Soft Contact Lens, Bausch + Lomb (Kalifilcon A) Soft Contact Lens for astigmatism

Jun 2, 2020
92 days to decision

K200528 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k200528/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Mar 2, 2020
Decision date	Jun 2, 2020
Days to decision	92 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 - NCT04158466

A Study to Evaluate the Safety and Efficacy of Kalifilcon A Daily Disposable Contact Lens

Status	Completed
Enrollment	252 patients (actual)
Study sites	16 sites
Condition studied	Contact Lens Wear
Primary purpose	Supportive_care
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Nov 12, 2019
Sponsor	Bausch & Lomb Incorporated (Industry)

Primary outcome

Mean logMAR Contact Lens Visual Acuity

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04158466