FDA 510(k) Premarket Notification

K222541 Bausch + Lomb Preservative Free Lubricating and Rewetting Drops

CLEARED

Dec 6, 2022
106 days to decision

K222541 · Product code: **LPN** · Ophthalmic
Source: https://www.510kdatabase.net/k222541/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	Aug 22, 2022
Decision date	Dec 6, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Incorporated**
Location	Rochester, NY, US
Contact	Melissa Thomas
510(k) history	27 submissions · 27 cleared · 2002-2024

CLINICAL EVIDENCE - NCT04175340

A Safety and Effectiveness Study of a New Preservative Free Rewetting Drop

Status	Completed
Enrollment	369 patients (actual)
Study sites	15 sites
Condition studied	Contact Lens Wear
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Feb 17, 2020
Sponsor	Bausch & Lomb Incorporated (Industry)

Primary outcome

Overall Comfort Averaged Over All Follow-up Visits

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04175340