

K202932 ABT12 multi-purpose solutionMay 28, 2021
241 days to decisionK202932 · Product code: **LPN** · Ophthalmic
Source: <https://www.510kdatabase.net/k202932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	Sep 29, 2020
Decision date	May 28, 2021
Days to decision	241 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 - NCT03897751

A Safety and Effectiveness Study of BL-ABT12 Multi-Purpose Solution for Use by Participants With Soft Contact Lenses

Status	Completed
Enrollment	252 patients (actual)
Study sites	17 sites
Condition studied	Contact Lens Wear
Primary purpose	Supportive_care
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Aug 1, 2019
Sponsor	Bausch & Lomb Incorporated (Industry)

Primary outcome**Overall Comfort**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03897751

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