

K222164 Visant Medical Canalicular PlugDec 23, 2022
155 days to decisionK222164 · Product code: **LZU** · Ophthalmic
Source: <https://www.510kdatabase.net/k222164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plug, Punctum (LZU)
Date received	Jul 21, 2022
Decision date	Dec 23, 2022
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visant Medical, Inc.
Location	Menlo Park, CA, US
Contact	Vartan Ghazarossian
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Pathways Group, Inc.
Contact	Lee Kramm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT04817085**An Evaluation of the Clinical Utility and Safety of the Visant Medical Canalicular Plug**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	156 patients (actual)
Study sites	5 sites
Condition studied	Dry Eye
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Feb 9, 2022
Sponsor	Visant Medical, Inc. (Industry)

Primary outcome

Mean change in Schirmer's score from baseline to Month 3 compared to commercially available plug

Secondary outcome

Proportion of responders achieving improvement from Baseline in Ocular Surface Disease Index (OSDI) score by a Minimal Clinically Important Difference (MCID).

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04817085