K191397 OxySoft (olifilcon C) silicone hydrogel soft contact lens

CLEARED

Oct 2, 2019
131 days to decision

K191397 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k191397/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	May 24, 2019
Decision date	Oct 2, 2019
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visco Vision, Inc.**
Location	New Taipei, Luzhou Dist, TW
Contact	Evan Huang
510(k) history	11 submissions · 11 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	**Jens Medical Consulting, Ltd.**
Contact	Jennifer Ting

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

CLINICAL EVIDENCE - NCT03934788

the Clinical Performance of the Oxysoft Daily Disposable Silicone Hydrogel Soft Contact Lens

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	36 patients (actual)
Study sites	3 sites
Condition studied	Myopia
Primary purpose	Supportive_care
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Nov 29, 2018
Sponsor	Visco Vision Inc. (Industry)

Primary outcome

Log MAR visual acuities

Secondary outcome

slit lamp findings

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03934788