

K223397 HOYA Illumina (sorafilcon A) Daily Disposable Soft Contact Lens, HOYA Illumina (sorafilcon A) Toric Daily Disposable Soft Contact Lens, HOYA Illumina (sorafilcon A) Multifocal Daily Disposable Soft Contact LensJan 3, 2024
421 days to decisionK223397 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k223397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Nov 8, 2022
Decision date	Jan 3, 2024
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hoya Lamphun , Ltd.
Location	Amphur Muang, TH
Contact	Timothy Ting
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT03859440**Three-month Clinical Evaluation of DSiHy Daily Disposable Silicone Hydrogel Contact Lenses**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	90 patients (estimated)
Condition studied	Contact Lenses
Primary purpose	Supportive_care
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Oct 1, 2019
Sponsor	HOYA Lamphun Ltd (Industry)

Primary outcome

Lens-related ocular adverse events requiring temporary or permanent discontinuation (resting eyes) as a proportion of follow-up eye examinations.

Secondary outcome

The following variables will be compared between lens types: Corneal staining - type (mean grade, 0-4)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03859440