

K232139 Innova Vision (inifilcon A) Silicone Hydrogel Soft (Hydrophilic) Contact LensNov 16, 2023
121 days to decisionK232139 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k232139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jul 18, 2023
Decision date	Nov 16, 2023
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innova Vision, Inc.
Location	Flagstaff, AZ, US
Contact	Celine Hsu
510(k) history	11 submissions · 11 cleared · 2004-2024

REGULATORY CONSULTANT

Consulting firm	Eyereg Consulting, Inc.
Contact	Bret Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT05395884****[Trial of device that is not approved or cleared by the U.S. FDA]**

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05395884510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), [ClinicalTrials.gov](https://clinicaltrials.gov) (U.S. National Library of Medicine).
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