FDA 510(k) Premarket Notification

K251876 cleadew GP hydra one

CLEARED

Oct 9, 2025
113 days to decision

K251876 · Product code: **MRC** · Ophthalmic
Source: https://www.510kdatabase.net/k251876/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Products, Contact Lens Care, Rigid Gas Permeable (MRC)
Date received	Jun 18, 2025
Decision date	Oct 9, 2025
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ophtecs Corporation**
Location	Kobe, JP
Contact	Takeichi Ryohei
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Andre Vision and Device Research**
Contact	Bret Andre

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

CLINICAL EVIDENCE - NCT06626009

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - *No results published to ClinicalTrials.gov*
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06626009