

**K251876 cleadew GP hydra one**Oct 9, 2025  
113 days to decisionK251876 · Product code: **MRC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k251876/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Andre Vision and Device Research</b>
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 - NCT06626009**

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**[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/NCT06626009](https://clinicaltrials.gov/study/NCT06626009)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251876/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)), [ClinicalTrials.gov](https://clinicaltrials.gov) (U.S. National Library of Medicine).  
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