

**K253352 Pegavision (Polymacon) Daily Disposable Soft (Hydrophilic) Contact Lenses**May 21, 2026  
233 days to decisionK253352 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k253352/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Sep 30, 2025
Decision date	May 21, 2026
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pegavision (Polymacon) Soft (Hydrophilic) Contact Lenses; Pegavision (Polymacon) Color Daily Disposable Soft (Hydrophilic) Contact Lenses; Pegavision (Polymacon) Color Soft (Hydrophilic) Contact Lenses

**APPLICANT**

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Company	<b>Pegavision Corporation</b>
Location	Taoyuan City, TW
Contact	Estela Lin
Website	<a href="https://www.pegavision.com">https://www.pegavision.com</a>
510(k) history	14 submissions · 14 cleared · 2012-2026

Pegavision Corporation is a contact lens manufacturer with a manufacturing facility in Taoyuan City, Taiwan. The company specializes in soft contact lens design and production for vision correction. Pegavision has received FDA 510(k) clearances from total submissions since 2012. The company focuses exclusively on Ophthalmic devices, with a strong track record in daily disposable and scheduled replacement soft contact lenses. The latest clearance was in 2026, confirming active regulatory engagement. The company's product portfolio includes daily disposable soft contact len...