

**K140025 AQUAMAX (ETAFILCON A) BI-WEEKLY DISPOSABLE  
SOFT (HYDROPHILIC) CONTACT LENSES**Oct 15, 2014  
282 days to decisionK140025 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k140025/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jan 6, 2014
Decision date	Oct 15, 2014
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pegavision Corporation</b>
Location	Taoyuan City, TW
Contact	TONY HSU
Website	<a href="https://www.pegavision.com">https://www.pegavision.com</a>
510(k) history	12 submissions · 12 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...