

# K211448 Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses

Dec 6, 2021  
210 days to decision

K211448 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k211448/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	May 10, 2021
Decision date	Dec 6, 2021
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## 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	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...