

K161739 Aquamax (Etafilcon A) Bi-Weekly Soft, Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

Dec 19, 2016
178 days to decision

K161739 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k161739/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jun 24, 2016
Decision date	Dec 19, 2016
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pegavision Corporation
Location	Taoyuan City, TW
Contact	Judith Hou
Website	https://www.pegavision.com
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...