FDA 510(k) Premarket Notification

CLEARED

K232649 Pegavision (Hioxifilcon A) Daily Disposable Soft Contact Lenses

May 8, 2024
251 days to decision

K232649 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k232649/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Aug 31, 2023
Decision date	May 8, 2024
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pegavision Corporation**
Location	Taoyuan City, TW
Contact	Estela Lin
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...