

**K242916 Largan U38 Color (Polymacon) Daily Wear Soft (hydrophilic) Contact Lens**Feb 4, 2025  
133 days to decisionK242916 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k242916/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Sep 24, 2024
Decision date	Feb 4, 2025
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Largan Medical Co., Ltd.</b>
Location	Taichung, TW
Contact	Shih-min Chen
510(k) history	8 submissions · 8 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242916/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026