

**K213216 Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens**Jan 18, 2022  
111 days to decisionK213216 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k213216/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Sep 29, 2021
Decision date	Jan 18, 2022
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Unicon Optical Co., Ltd.</b>
Location	New Taipei, TW
Contact	Nick Liao
510(k) history	5 submissions · 5 cleared · 2014-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Eyereg Consulting, Inc.</b>
Contact	Bret Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213216/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026