FDA 510(k) Premarket Notification

CLEARED

K213216 Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens

Jan 18, 2022
111 days to decision

K213216 · 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	**Unicon Optical Co., Ltd.**
Location	New Taipei, TW
Contact	Nick Liao
510(k) history	5 submissions · 5 cleared · 2014-2024

REGULATORY CONSULTANT

Consulting firm	**Eyereg Consulting, Inc.**
Contact	Bret Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov