

K241707 OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™Jul 12, 2024
29 days to decisionK241707 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k241707/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jun 13, 2024
Decision date	Jul 12, 2024
Days to decision	29 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	Andre Vision and Device Research
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)

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