

K243953 Aurora (ocufilcon D) Soft (Hydrophilic) Daily Wear Contact Lens (Tinted, Color)Apr 10, 2025
108 days to decisionK243953 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k243953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Dec 23, 2024
Decision date	Apr 10, 2025
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vizionfocus, Inc.
Location	Zhunan Township, TW
Contact	Angus Shih
510(k) history	5 submissions · 5 cleared · 2018-2025

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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