FDA 510(k) Premarket Notification

CLEARED

K233325 Visionary Optics Scleral Contact Lens (roflufocon D, roflufocon E, hexafocon A, hexafocon B, tisilfocon A, fluoroxyfocon A)

Feb 21, 2024
145 days to decision

K233325 · Product code: **HQD** · Ophthalmic
Source: https://www.510kdatabase.net/k233325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Sep 29, 2023
Decision date	Feb 21, 2024
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visionary Optics, LLC**
Location	Front Royal, VA, US
Contact	Donald Sanders
510(k) history	3 submissions · 3 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Andrew 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