

**K230910 NewVision SC (tisilfocon A) Scleral Lens**Jun 16, 2023  
77 days to decisionK230910 · Product code: **HQD** · Ophthalmic  
Source: <https://www.510kdatabase.net/k230910/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Mar 31, 2023
Decision date	Jun 16, 2023
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens

**APPLICANT**

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Company	<b>Acculens, Inc.</b>
Location	Lakewood, CO, US
Contact	Troy Miller
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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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)

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