

**K221659 Luminopia One**Nov 4, 2022  
149 days to decisionK221659 · Product code: **QQU** · Ophthalmic  
Source: <https://www.510kdatabase.net/k221659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapy Device For Amblyopia (QQU)
Date received	Jun 8, 2022
Decision date	Nov 4, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Luminopia, Inc.</b>
Location	Cambridge, MA, US
Contact	Scott Xiao
510(k) history	4 submissions · 3 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221659/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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