

K243729 PrismiraJun 13, 2025
192 days to decisionK243729 · Product code: **QFT** · Neurology
Source: <https://www.510kdatabase.net/k243729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapeutic Software For Attention Deficit Hyperactivity Disorder (QFT)
Date received	Dec 3, 2024
Decision date	Jun 13, 2025
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lumos Labs, Inc.
Location	San Francisco, CA, US
Contact	Robert (Bob) Schafer
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Aepis Medical
Contact	Adam Savakus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243729/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026