FDA 510(k) Premarket Notification

K254086 EyeBOX SNAP

CLEARED

Jun 5, 2026
169 days to decision

K254086 · Product code: **QEA** · Neurology
Source: https://www.510kdatabase.net/k254086/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Oculomotor Assessment Aid (QEA)
Date received	Dec 18, 2025
Decision date	Jun 5, 2026
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oculogica, Inc.**
Location	New York, NY, US
Contact	Rosina Samadani
510(k) history	6 submissions · 5 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells**
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov