FDA 510(k) Premarket Notification

K242116 EyeBOX EBX-4.1

CLEARED

Apr 4, 2025
259 days to decision

K242116 · Product code: **QEA** · Neurology
Source: https://www.510kdatabase.net/k242116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Oculomotor Assessment Aid (QEA)
Date received	Jul 19, 2024
Decision date	Apr 4, 2025
Days to decision	259 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	5 submissions · 4 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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