FDA 510(k) Premarket Notification

K212310 EyeBOX (Model EBX-4)

CLEARED

Dec 22, 2021
152 days to decision

K212310 · Product code: **QEA** · Neurology
Source: https://www.510kdatabase.net/k212310/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Oculomotor Assessment Aid (QEA)
Date received	Jul 23, 2021
Decision date	Dec 22, 2021
Days to decision	152 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