

**K212310 EyeBOX (Model EBX-4)**Dec 22, 2021  
152 days to decisionK212310 · Product code: **QEA** · Neurology  
Source: <https://www.510kdatabase.net/k212310/>**SUBMISSION DETAILS**

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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**

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Company	<b>Oculogica, Inc.</b>
Location	New York, NY, US
Contact	Rosina Samadani
510(k) history	5 submissions · 4 cleared · 2018-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice Hogan

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212310/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026