

**K191183 EyeBOX**Jul 31, 2019  
90 days to decisionK191183 · Product code: **QEA** · Neurology  
Source: <https://www.510kdatabase.net/k191183/>**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	May 2, 2019
Decision date	Jul 31, 2019
Days to decision	90 days
Third-party review	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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191183/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026