

**K210831 OnQ Neuro**Nov 19, 2021  
245 days to decisionK210831 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k210831/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 19, 2021
Decision date	Nov 19, 2021
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cortechs Labs, Inc.</b>
Location	Charlestown, MA, US
Contact	Kora Marinkovic
510(k) history	7 submissions · 7 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210831/> 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