

**K191868 iCEWav Neuromonitoring Platform**Mar 31, 2020  
263 days to decisionK191868 · Product code: **GWQ** · Neurology  
Source: <https://www.510kdatabase.net/k191868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Jul 12, 2019
Decision date	Mar 31, 2020
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ice Neurosystems, Inc.</b>
Location	Washington, DC, US
Contact	Allen Waziri
510(k) history	3 submissions · 3 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191868/> 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 24, 2026