

**K163324 nordicBrainEx**Jan 27, 2017  
63 days to decisionK163324 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k163324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 25, 2016
Decision date	Jan 27, 2017
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nordicneurolab AS</b>
Location	Bergen, NO
Contact	CHANDANA GURUNG BHANDARI
510(k) history	7 submissions · 7 cleared · 2017-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163324/> 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 16, 2026