

**K252565 PreOp v3**

Feb 13, 2026  
183 days to decision

K252565 · Product code: **OLX** · Neurology  
Source: <https://www.510kdatabase.net/k252565/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Source Localization Software For Electroencephalograph Or Magnetoencephalograph (OLX)
Date received	Aug 14, 2025
Decision date	Feb 13, 2026
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clouds of Care</b>
Location	Ghent, BE
Contact	Gregor Strobbe
510(k) history	1 submissions · 1 cleared · 2026-2026

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