

K233908 cNeuro cDATJul 1, 2024
202 days to decisionK233908 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k233908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 12, 2023
Decision date	Jul 1, 2024
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Combinostics OY
Location	Tampere, FI
Contact	Lennart Thurfjell
510(k) history	3 submissions · 3 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Erin Gontang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233908/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026