

K252922 Neosoma Brain Mets

Dec 17, 2025
93 days to decision

K252922 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252922/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 15, 2025
Decision date	Dec 17, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neosoma, Inc.
Location	Groton, MA, US
Contact	Kenneth Kolodziej
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Innolitics, LLC
Contact	Meritxell Martinez

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
