

K252496 Neurophet AQUA AD PlusJan 29, 2026
174 days to decisionK252496 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 8, 2025
Decision date	Jan 29, 2026
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurophet., Inc.
Location	Seoul, KR
Contact	Yerim Lee
510(k) history	4 submissions · 4 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Global Medical Standard Consulting Co., Ltd.
Contact	Jonghyun Kim

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

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