

K261273 Neurophet AQUAMay 15, 2026
28 days to decisionK261273 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k261273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 17, 2026
Decision date	May 15, 2026
Days to decision	28 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	6 submissions · 6 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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