

K260455 New Wave SystemMar 13, 2026
30 days to decisionK260455 · Product code: **GWQ** · Neurology
Source: <https://www.510kdatabase.net/k260455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Feb 11, 2026
Decision date	Mar 13, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zeto, Inc.
Location	Raleigh, NC, US
Contact	Florian Strelzyk
510(k) history	3 submissions · 3 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Innolitics, LLC
Contact	Ameera Roubi

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

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