

K243709 NeuroEars-Anna™Aug 25, 2025
266 days to decisionK243709 · Product code: **GWN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k243709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Dec 2, 2024
Decision date	Aug 25, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neuroears, Inc.
Location	Gangwon-Do, KR
Contact	Suh Kyoowon
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Hannah Taggart

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

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