

K250153 Neu PlatformApr 25, 2025
94 days to decisionK250153 · Product code: **GYD** · Neurology
Source: <https://www.510kdatabase.net/k250153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Jan 21, 2025
Decision date	Apr 25, 2025
Days to decision	94 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neuhealth Digital , Ltd.
Location	London, GB
Contact	Giovanni Maggi
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250153/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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