FDA 510(k) Premarket Notification

K250153 Neu Platform

CLEARED

Apr 25, 2025
94 days to decision

K250153 · 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