April 25, 2025

Neuhealth Digital Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Boulevard
Warren, New Jersey 07059

Re: K250153
Trade/Device Name: Neu Platform
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor transducer
Regulatory Class: Class II
Product Code: GYD
Dated: March 5, 2025
Received: March 6, 2025

Dear Dave Yungvirt:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250153

Device Name

Neu Platform

Indications for Use *(Describe)*

The Neu Platform is intended to quantify the kinematics of movement disorder symptoms, including tremor in adults (45 years and older) with mild to moderate Parkinson's disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Submitter Information:

Name:	Neuhealth Digital Ltd.
Address:	10 Fitzroy Square, London, W1T 5HP, United Kingdom
Establishment Registration Number:	3032027298
Owner/Operator Number:	10091292
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Contact:	Giovanni Maggi, Senior Manager of Quality and Regulatory
E-mail:	giovanni.maggi@neu.health
Date of Summary:	14-Jan-2025

Device Information:

Below summarises the Device Classification information regarding the Neu Platform.

Device Proprietary Name	Neu Platform
Common Name:	Tremor Transducer
Trade Name:	Neu Platform
Product Code(s):	GYD

Primary Product Code

Regulation Number (21 CFR)	Device	Product Class	Product Code	Classification Panel
882.1950	Tremor Transducer	Class II	GYD	Neurology

Substantial Equivalence

Manufacturer	Trade Name	Regulation & Product Code	510(k) Number
H2O Therapeutics	Parky App	882.1950 GYD, NXQ, ISD	K220820

Submission Description

This traditional 510(k) presents a new medical device for the measurement of tremor for patients with Parkinson's Disease. Well-established methods have been used to evaluate the change and the date to be reviewed is provided in a summary in this submission.

Device Description

General Description

The Neu Platform is a platform designed to capture digital motor and patient-reported data in patients with mild to moderate Parkinson's Disease. The platform has two key components:

- **A smartphone application for the remote capture of symptoms** - Patients utilise the smartphone application to perform the motor tremor measurement activities. The app is also used for the patient to self-reported data, including onboarding information and subjective symptom information,
- **A dashboard for the clinical team to view the captured data** - The clinician dashboard presents the data to clinical staff responsible for managing the patient's condition for review.

The Platform is comprised of a patient app, supporting backend infrastructure, and a clinician web-based dashboard. The Neu Platform is related to the components of the platform specifically for data capture from patients with Parkinson's disease. The smartphone application and clinical dashboard have been developed and validated with extensive input from patients and clinicians.

Figure 1 provides a high level schematic of the system, components and operation.

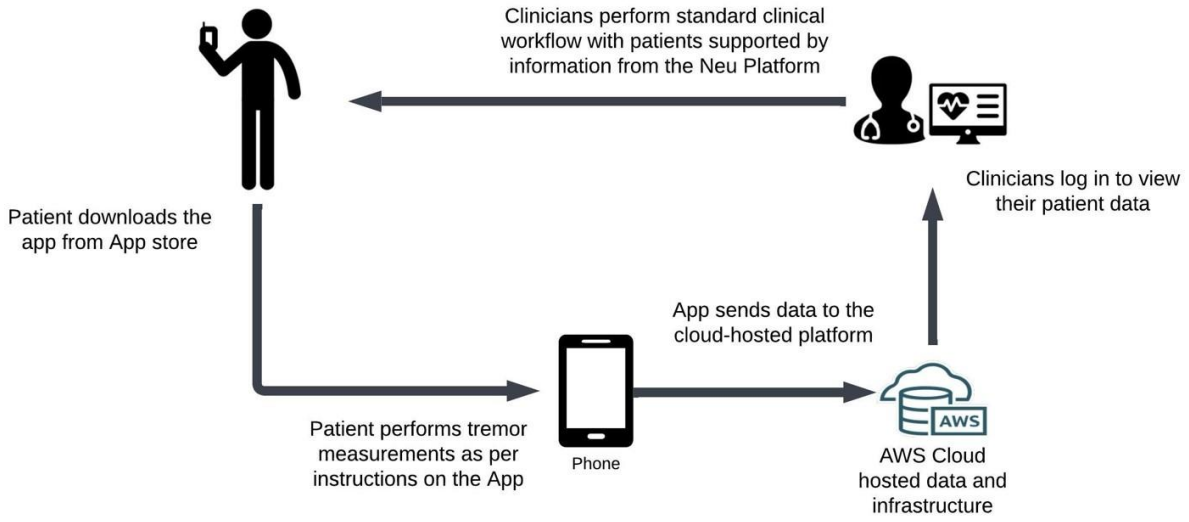

Figure 1: High Level Overview of the Neu Platform

Intended/ Indications for Use

The Neu Platform is intended to quantify the kinematics of movement disorder symptoms, including tremor in adults (45 years and older) with mild to moderate Parkinson's disease.

Comparison with the Predicate and Previously Cleared Device

The proposed device is substantially equivalent to the predicate, K220820, the Parky App and a comparison of the key characteristics is summarised in Table 1. The devices are similar in terms of indications for use, technological characteristics and performance data and therefore there are no new or different questions and effectiveness.

Characteristic	Subject Device Neu Platform	Predicate Device Parky App – K220820	Equivalence Comparison
Intended Use	To measure the degree of tremor caused by certain diseases.	To measure the degree of tremor caused by certain diseases.	Same as the predicate
Indications for Use	The Neu Platform is intended to quantify the kinematics of movement disorder symptoms, including tremor in	The Parky App is intended to quantify kinematics of movement disorder symptoms including	Similar to the predicate; both the Subject and Predicate device measure tremor. The subject device

Characteristic	Subject Device Neu Platform	Predicate Device Parky App – K220820	Equivalence Comparison
	adults (45 years and older) with mild to moderate Parkinson's disease.	tremor and dyskinesia, in adults (45 years of age or older) with mild to moderate Parkinson's disease.	does not measure dyskinesia.
Rx vs OTC	Rx	Rx	Same as the predicate
Patient Population	45+ with mild to moderate Parkinson's disease.	45+ with mild to moderate Parkinson's disease.	Same as the predicate
Use Environment	Home and clinic.	Home and clinic.	Same as the predicate
Measurement method	Accelerometer in commercial off the shelf digital device.	Accelerometer in commercial off the shelf digital device.	Same as the predicate
Functionality	Measurement of tremor using accelerometer within digital device; recording of medication, report symptoms and questionnaires.	Measurement of tremor using accelerometer within digital device; recording of medication, report symptoms and questionnaires.	Same as the predicate
Software	Software validation conducted as per FDA Guidance 'Content of premarket submissions for Device Software Functions', issued May 11, 2005.	Software validation conducted as per FDA Guidance 'Content of premarket submissions for Device Software Functions', issued May 11, 2005.	Same as the predicate
Hardware/Software	Mobile Phone with internet access. Min OS – iOS 14.1; Android 7.	Apple watch Mobile Phone with internet access.	Similar to the predicate – both devices use off the shelf mobile software and hardware and transmit that using internet.
Cybersecurity	Cybersecurity threat analysis and mitigation has been conducted according to "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".	Cybersecurity threat analysis and mitigation has been conducted according to "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".	Same as the predicate
Cybersecurity & Encryption authentication	Data encrypted TLS-1.2+ and AES-256. Patient and clinician secure access with MFA.	Not specified.	All data is encrypted in transit and at rest throughout the system
Outputs and features	Measure and quantify degree of tremor.	Measure and quantify degree of tremor.	Same as the predicate

Characteristic	Subject Device Neu Platform	Predicate Device Parky App – K220820	Equivalence Comparison
Diagnosis or treatment recommendations	No	No	Same as the predicate
Data transmission	Cellular or wireless network.	Cellular or wireless network.	Same as the predicate
Off-the-Shelf Software	Utilizes Apple and Android OS and accelerometer to measure and quantify tremor related to Parkinson's Disease.	Utilizes Apple's MM4PD API and Apple Watch's accelerometer to measure and quantify dyskinesia and tremor related to Parkinson's Disease.	Similar to the predicate; both devices use the accelerometers in mobile devices to perform the measurement
Performance data	Device measurements highly correlated to measurements of tremor severity. Correlation of 0.92 ($p<0.01$) and 0.85 ($p=0.002$) between the tremor measurement and the clinical standard for the rest and postural tremor measurements respectively.	Device Measurements highly correlated to clinical evaluations of tremor severity (Rank Correlation Coefficient=0.80) and mapped to expert ratings of dyskinesia presence ($P<0.001$) during in-clinic tasks. Device captured symptom changes in response to treatment that matched the clinician's expectations in 94% of evaluated subjects.	Similar to the predicate
Patient Interface	Stand-alone software running on general purpose commercial off-the-shelf mobile smartphones. Display of tremor activity, medication information and other information.	Stand-alone software running on general purpose commercial off-the-shelf mobile smartphones. Display of tremor activity, medication information and other information.	Same as the predicate
Healthcare Professional interface	Data stored in remote central database (i.e., Cloud). Information accessed by clinician via web portal.	Data stored in remote central database (i.e., Cloud). Information accessed by clinician via web portal.	Same as the predicate

Table 1: Comparison of characteristics between the Subject Device and the Predicate Device.

Technological Characteristics

Intended Use

The subject device and the predicate device both measure the kinematics of movement disorders, specifically tremor for patients with mild to moderate Parkinson's Disease. Both devices capture the measurements through the accelerometers in commercial digital personal devices.

The Neu Platform does not currently detect dyskinesia, so this symptom measurement is removed. However, this can still be assessed clinically by the clinicians and/or reported by the patient, so this change does not constitute a change in the type or level of risk compared to the predicate device.

Neither the Subject device nor the Predicate device provide diagnosis or contain results that provide any diagnostics or treatment recommendations.

Principle of operation and technology used

The Subject and Predicate Devices use a mobile device such as smartphone/watch and its sensors (e.g., accelerometer, touchscreen) to administer, measure and collect various tasks and data from a patient, storing the data remotely and present that information to the patient or healthcare professional for review and tracking.

The Subject and Predicate devices are stand-alone software applications that use off-the-shelf general-purpose devices such as mobile phones or tablets to collect data and display information.

The Subject device offers similar measurement and assessment of symptoms as the Predicate device which are then displayed for the patient and sent to a clinician for review. All data is stored in central database and available for access on demand.

The Subject device and the Predicate device both offer similar feature of allowing the patient to frequently perform tasks, report symptoms or respond to questionnaires.

Software and Cybersecurity

The subject device used the same FDA Guidance and International Standards for software development process (IEC 62304) software documentation (Content of Premarket Submissions for Device Software Functions), Risk Management process (IEC 14971), cybersecurity (Content of Premarket Submissions for Management of Cybersecurity in Medical Devices).

Summary of Performance Data

The performance data demonstrates that the Neu Health tremor measurements are in agreement with clinically meaningful differences in tremor severity and therefore is substantially equivalent in performance with the predicate device. Both devices display significant correlation with the accepted clinical standard (MDS-UPDRS).

Bench testing validated our devices tremor measurements by comparing the results of our tremor measurements, obtained in a controlled setting, to the same clinical standard as the predicate device (tremor severity as defined by the UPDRS-III assessment). In our bench testing, we observed a correlation of 0.92 ($p<0.01$) and 0.85 ($p=0.002$) between the tremor measurement and the clinical standard for the rest and postural tremor measurements respectively. These strong correlations demonstrate that our device is capable of detecting changes in tremor at the equivalent, or greater, level of accuracy as the predicate device ($r=0.72$).

This supports that the Neu Platform is an effective tool for assessing tremor in patients with mild to moderate Parkinson's Disease. The performance is deemed substantially equivalent to those presented by the predicate device.

Summary of Animal & Clinical Studies

Substantial equivalence is based on an assessment of non-clinical performance data and no animal or clinical performance data is included.

Conclusion

Based on the information presented in this Traditional 510(k) submission, the Neu Platform, is substantially equivalent to the predicate device (Parky App) in terms of safety, performance, functionality, and indications for use and is as safe and effective for its intended use.