August 20, 2026

Kneu Health Digital , Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
1887 Whitney Mesa Dr.
Suite 1960
Henderson, Nevada 89014

Re: K262515
Trade/Device Name: Kneu Platform (V2)
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor transducer
Regulatory Class: Class II
Product Code: GYD, NXQ, ISD
Dated: July 20, 2026
Received: July 21, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Patrick Antkowiak -S

Patrick Antkowiak
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.

510(k) Number *(if known)*

Device Name

Kneu Platform V2

Indications for Use *(Describe)*

The Kneu Platform is intended to quantify the kinematics of movement disorder symptoms, including tremor and dyskinesia, 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 submitted in accordance with 21 CFR 807.92. The summary retains the structure of the previous 510(k) Summary draft, but the content has been rebuilt from the current Kneu Platform Device Description and Substantial Equivalence rationale.

Submitter Information

Item	Information
Name	Kneu Health Digital Ltd.
Address	Blackwell House, Guildhall Yard, London, United Kingdom EC2V 5AE
Establishment Registration Number	3032027298
Owner/Operator Number	10091292
Phone	+44 0330 0430 939
Contact	Alessia Nannetti, Quality and Regulatory Lead
E-mail	alessia.nannetti@kneu.com
Date of Summary	20 July 2026

Device Information

Item	Information
Device Proprietary Name	Kneu Platform V2
Common Name	Tremor Transducer
Trade Name	Kneu Platform
Primary Product Code	GYD
Additional product codes included for completeness	NXQ medication reminder and ISD step count are supportive, informational functions. They are described for completeness and are not relied on to generate diagnostic or treatment recommendations.

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 and Product Code	510(k) Number	Use in this submission
H2O Therapeutics	Parky App	21 CFR 882.1950; GYD, NXQ, ISD	K220820	Predicate for Apple Watch passive tremor and dyskinesia monitoring using Apple MM4PD / Movement Disorder APIs and for the supportive NXQ/ISD functions.
Neuhealth Digital Ltd. / Kneu Health Digital	Neu Platform / Kneu Platform	21 CFR 882.1950; GYD	K250153	Predicate for unchanged active smartphone-based tremor measurement, patient app, clinician

				dashboard, and cloud-hosted platform.

Submission Description

This Traditional 510(k) describes a modification to the previously cleared Kneu / Neu Platform (K250153). The previously cleared active smartphone-based tremor assessment, patient smartphone application, clinician dashboard, and cloud infrastructure remain substantially unchanged. The modification adds passive tremor and dyskinesia monitoring for iOS users with a compatible paired Apple Watch. Passive outputs are generated by Apple's Movement Disorder APIs / MM4PD and transferred through the paired iPhone app to the Kneu backend and clinician dashboard. The submission also describes medication reminder (NXQ) and step count (ISD) functions as supportive, informational functions.

Device Description

General Description

The Kneu Platform V2 is a stand-alone software medical device platform intended for adults with mild to moderate Parkinson's disease and the healthcare professionals involved in their care. The platform captures active smartphone-based rest and postural tremor assessments, patient-reported information, medication information, and, for compatible iPhone/Apple Watch users, passive tremor and dyskinesia outputs generated by Apple's Movement Disorder APIs / MM4PD.

The platform comprises a patient smartphone app, a minimal bundled Apple Watch companion app used for passive-monitoring setup/status and local data transfer support, cloud-hosted backend services, and a clinician web dashboard. Kneu does not implement, train, or modify the Apple MM4PD algorithm. Passive monitoring is supplementary to active assessments and clinical judgement and does not generate diagnostic or treatment recommendations.

- Patient smartphone app: onboarding, active tremor assessments, patient-reported symptoms and questionnaires, medication diary/reminders, Apple Watch monitoring setup, and patient-facing insights.
- Apple Watch passive monitoring: background collection of tremor and dyskinesia outputs generated by Apple's Movement Disorder APIs / MM4PD, with local queueing and transfer to the paired iPhone app.
- Cloud-hosted backend: secure storage, aggregation, auditability, and retrieval of active and passive data for presentation.
- Clinician dashboard: presentation of active tremor information and a dedicated Passive Motor Signals / passive results area with tremor and dyskinesia trends, monitoring wear time, data availability, and medication-context indicators where applicable.

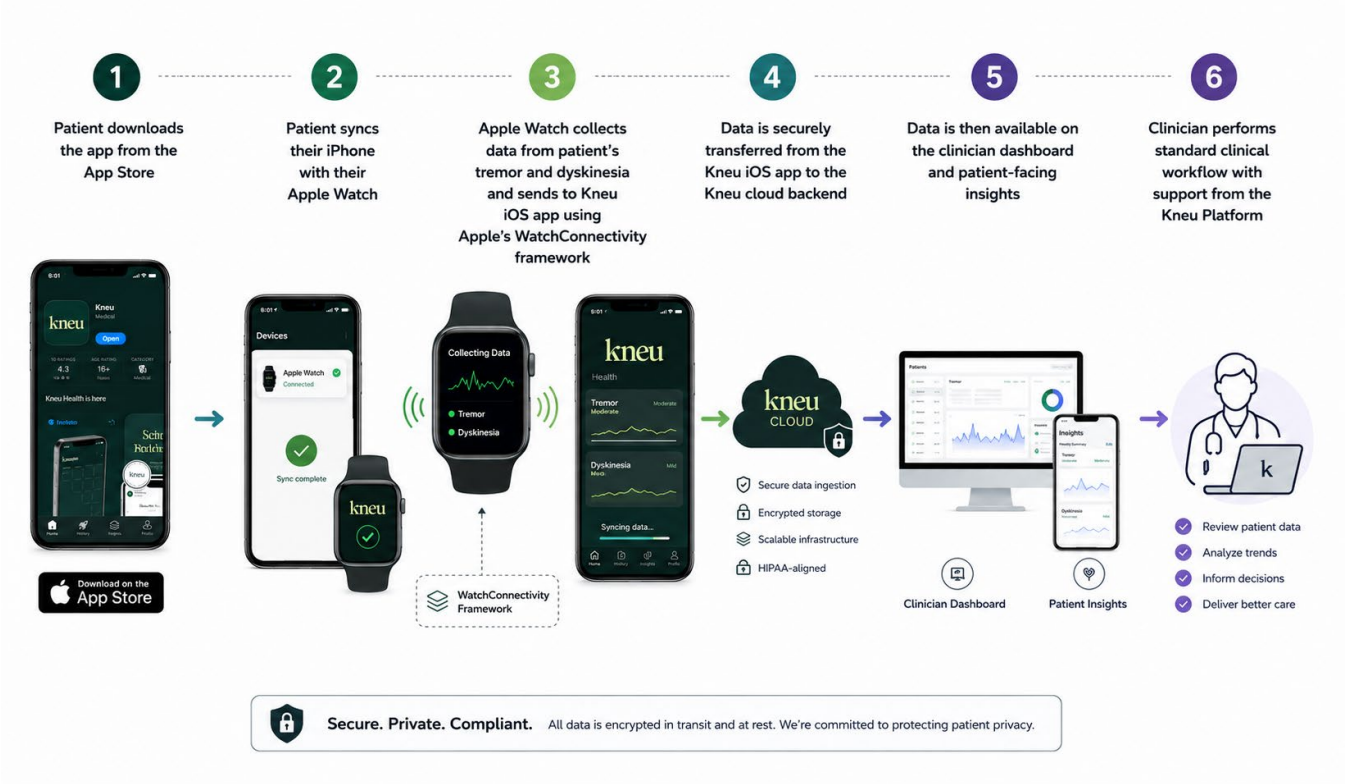

Figure 1: High-level overview of the Kneu Platform from the Device Description.

Intended / Indications for Use

The Kneu Platform is intended to quantify the kinematics of movement disorder symptoms, including tremor and dyskinesia, 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 previously cleared Kneu / Neu Platform (K250153) for the unchanged active tremor functionality and substantially equivalent to Parky App (K220820) for Apple Watch passive tremor and dyskinesia monitoring. The comparison below summarizes the key characteristics.

Characteristic	Subject Device - Kneu Platform V2	Primary Predicate - Parky App (K220820)	Reference Predicate - Kneu / Neu Platform (K250153)	Equivalence
Intended Use	To measure the degree of tremor and dyskinesia caused by certain diseases	To measure the degree of tremor and dyskinesia caused by certain diseases	To measure the degree of tremor caused by certain diseases	Equivalent to Primary Predicate
Indications for Use	The Kneu Platform V2 is intended to quantify the kinematics of movement disorder symptoms,	The Parky App is intended to quantify kinematics of movement disorder	The Kneu Platform is intended to quantify the kinematics of movement disorder	Substantially equivalent. The addition of dyskinesia measurement aligns the subject device

	including tremor and dyskinesia, in adults (45 years and older) with mild to moderate Parkinson's disease.	symptoms including tremor and dyskinesia, in adults (45 years of age or older) with mild to moderate Parkinson's disease.	symptoms, including tremor in adults (45 years and older) with mild to moderate Parkinson's disease.	indications for use with Primary Predicate. Both Subject Device and Primary Predicate measure tremor and dyskinesia in the same patient population.
Rx vs OTC	Rx	Rx	Rx	Equivalent
Use Environment	Home and clinic	Home and clinic	Home and clinic	Equivalent
Active Measurement Method	Accelerometer in commercial off-the-shelf smartphone	N/A (watch based only)	Accelerometer in commercial off the shelf digital device	Equivalent as Reference Predicate
Passive Measurement Method	Utilizes Apple's Movement Disorder Management (MM4PD) API and Apple Watch's accelerometer to measure and quantify dyskinesia and tremor	Utilizes Apple's Movement Disorder Management (MM4PD) API and Apple Watch's accelerometer to measure and quantify dyskinesia and tremor	N/A	Equivalent as Primary Predicate: same Apple Watch hardware class and Apple's Movement Disorder Management (MM4PD) API
Functionality	Active tremor assessment; passive tremor and dyskinesia monitoring; patient-reported information; medication reminders; step count.	Active tremor assessment and patient-reported information.	Passive tremor/dyskinesia monitoring; medication reminders; step count.	Combination of unchanged Reference Predicate functionality and Primary Predicate passive/supportive functionality.
Outputs and Features	Measure and quantify degree of tremor and dyskinesia; percentage of time tremor and dyskinesia were likely to occur	Measure and quantify degree of tremor and dyskinesia; percentage of time tremor and dyskinesia were likely to occur	Measure and quantify degree of tremor	Equivalent as Reference Predicate for active outputs; equivalent as Primary Predicate for passive outputs, medication reminders, and step count
Software	Software validation conducted as per FDA Guidance 'Content of Premarket Submissions for Device Software Functions', issued June 14, 2023	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 SoftwareFunctions', issued May 11, 2005	Substantially equivalent
Cybersecurity	Cybersecurity threat analysis and mitigation conducted according to FDA cybersecurity guidance. Data encrypted in transit using TLS and at rest using AES-256. Patient and clinician access authenticated; APIs use OAuth 2.0/JWT authorization. Threat model updated for Apple Watch / Apple framework inputs, local queueing, and phone-to-cloud transfer pathway.	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 conducted according to "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". Data encrypted TLS-1.2+ and AES-256.	Equivalent

Performance data – Tremor and Dyskinesia	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). Symptom changes matched clinician expectations in 94% of evaluated subjects. (Powers et al Study)	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). Symptom changes matched clinician expectations in 94% of evaluated subjects. (Powers et al Study)	n/a	Equivalent – identical performance using Apple's Movement Disorder API
Performance Data – Active Tremor	Device measurements highly correlated to clinical evaluations of tremor severity. Correlation of 0.92 (p<0.01) and 0.85 (p=0.002) between tremor measurement and clinical standard.	n/a	Device measurements highly correlated to clinical evaluations of tremor severity. Correlation of 0.92 (p<0.01) and 0.85 (p=0.002) between tremor measurement and clinical standard.	Equivalent – unchanged functionality
Patient Interface	Stand-alone software running on general purpose commercial off-the-shelf smartphones (iOS and Android), with iOS-only bundled Apple Watch companion app for passive monitoring setup/status and patient-facing Apple Watch results views.	Stand-alone software running on general purpose commercial off-the-shelf mobile smartphones.	Stand-alone software running on general purpose commercial off-the-shelf mobile smartphones.	Equivalent as Reference Predicate for existing smartphone app; equivalent as Primary Predicate for Apple Watch passive monitoring interface
Healthcare Professional Interface	Data stored in remote cloud databases. Information accessed by clinician via web portal, including active tremor outputs and passive tremor/dyskinesia dashboard module with time-based charts and data coverage context.	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.	Equivalent; presentation is via web portal rather than email report and does not change the underlying measurement method

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

Technological Characteristics

Intended Use

The Subject Device and predicate devices quantify movement disorder symptoms in adults with mild to moderate Parkinson's disease. The existing active tremor assessment is unchanged from K250153. The

passive tremor and dyskinesia monitoring uses the same Apple Watch hardware and Apple MM4PD / Movement Disorder API approach as K220820. Neither the Subject Device nor the predicate devices provide diagnosis or treatment recommendations.

Principle of Operation and Technology Used

The Subject Device uses off-the-shelf smartphones for active assessments and, for compatible iOS users, an off-the-shelf Apple Watch for passive monitoring. Data are captured, transferred to the Kneu backend, securely stored and aggregated, and presented to patients and clinicians in human-readable visualizations. Passive tremor and dyskinesia data are supplementary to active assessments and clinical judgement.

Software and Cybersecurity

The Subject Device uses software lifecycle, risk management, and cybersecurity controls described in the Device Description and Substantial Equivalence documents, including IEC 62304 software development, ISO 14971-aligned risk management, requirements traceability, verification and validation, cybersecurity threat assessment, encryption, access control, and labeling controls.

Summary of Performance Data

Passive tremor and dyskinesia performance is supported by equivalence to Parky App (K220820), which uses the same Apple Watch hardware and Apple MM4PD / Movement Disorder API. Device measurements are highly correlated to clinical evaluations of tremor severity (Rank Correlation Coefficient = 0.80) and mapped to expert ratings of dyskinesia presence ($P<0.001$), with symptom changes matching clinician expectations in 94% of evaluated subjects (Powers et al). As the same Movement Disorder API is used, performance is identical to the predicate.

Active tremor performance remains based on the previously cleared Kneu / Neu Platform evidence and is unchanged. Device measurements are highly correlated to clinical evaluations of tremor severity, with correlations of 0.92 ($p<0.01$) and 0.85 ($p=0.002$) for rest and postural tremor measurements respectively against clinical standard assessments. This is equivalent to the predicate, with unchanged functionality.

Neither the Subject Device nor the predicate devices provide a diagnosis or treatment recommendation. Kneu presents passive outputs as supplementary trends and does not modify the MM4PD algorithm output into a diagnostic or treatment recommendation.

Summary of Animal and Clinical Studies

Substantial equivalence is supported by comparison to the predicate devices and by non-clinical, software, and performance evidence. No new animal studies are included. No additional Kneu clinical study is required for the passive Apple Watch functionality because equivalence is based on the same Apple MM4PD algorithm and Apple Watch hardware used by Primary Predicate, together with Kneu software verification of integration, transfer, storage, aggregation, and display.

Conclusion

Based on the information presented in this Traditional 510(k) submission, the Kneu Platform V2 is substantially equivalent to the predicate devices, Kneu / Neu Platform (K250153) and Parky App (K220820), in intended use, technological characteristics, safety, performance, and risk profile. The Apple Watch passive monitoring functionality and supportive NXQ/ISD functions do not introduce new or different questions of safety or effectiveness.