March 17, 2023

New Touch Digital Inc.
Chan Lee
Chief Operating Officer
3124 Dumbarton Street NW
Washington, District of Columbia 20007

Re: K221772
Trade/Device Name: NeuroRPM
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor Transducer
Regulatory Class: Class II
Product Code: GYD, ISD
Dated: February 15, 2023
Received: February 15, 2023

Dear Chan Lee:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221772

Device Name
NeuroRPM

Indications for Use *(Describe)*
NeuroRPM is intended to quantify movement disorder symptoms during wake periods in adult patients 46 to 85 years of age with Parkinson's disease. These symptoms include tremor, bradykinesia, and dyskinesia. NeuroRPM is intended for clinic and home environments.

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.

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K221772 Traditional 510(k) SUMMARY

New Touch Digital Inc.'s NeuroRPM

Submitter:

New Touch Digital Inc.
3124 Dumbarton Street NW
Washington, DC 20007

Contact Person: Chan Lee
Phone: (703)201-9548
Email: chan.lee@newtouchdigital.com

Date Prepared:	March 17, 2023
Name of Device:	NeuroRPM K221772
Common or Usual Name:	NeuroRPM
Classification Name:	Tremor Transducer 21 CFR 882.1950
Regulatory Class:	Class II
Primary Product Code:	GYD
Secondary Product Code:	ISD

Predicate Device:

Manufacturer:	GKC Manufacturing Pty Ltd.
Trade/Device Name:	Personal Kinetigraph (PKG) System Model GKC-2000
510(K) Number:	K161717
Decision Date:	September 20, 2016

Device Description:

NeuroRPM is a software application for the Apple Watch that is prescribed by a health professional to quantify motor symptoms of Parkinson's disease including bradykinesia, dyskinesia, and tremor. NeuroRPM collects accelerometer and gyroscope data from the Apple Watch. The motion data are transmitted to cloud servers and analyzed using machine learning models developed to generate binary symptom classifications. Binary symptom classification output is generated every 15-minutes. A description of the NeuroRPM outputs is provided in **Table 1**.

Table 1 - Description of NeuroRPM Outputs

Symptom	Output Classification	Output Description	Validated Scale
Tremor	NTD-TR A - No Tremor	No tremor detected.	UPDRS-III TR Score of 0
	NTD-TR B - Tremor	Tremor detected.	UPDRS-III TR Score of 1 and greater
Bradykinesia	NTD-BK A - Normal to Low	No, minor or mild bradykinesia detected.	Combined UPDRS-III BK Score of 0, 1, 2, 3
	NTD-BK B - Medium to High	Moderate or greater than moderate bradykinesia detected.	Combined UPDRS-III BK Score of 4 and greater
Dyskinesia	NTD-DK A - No Dyskinesia	No dyskinesia detected.	Total AIMS Score of 0, 1
	NTD-DK B - Dyskinesia	Dyskinesia detected.	Total AIMS Score of 2 and greater

Intended Use:

NeuroRPM is intended to quantify movement disorder symptoms during wake periods in adult patients 46 to 85 years of age with Parkinson's disease. These symptoms include tremor, bradykinesia, and dyskinesia. NeuroRPM is intended for clinic and home environments.

Summary of Technological Characteristics:

The proposed device and the predicate device have similar technological characteristics. Both devices obtain a patient's movement data from a wrist-worn device. Sensor data from both the proposed and predicate wrist-worn devices are transferred to a cloud server and analyzed using algorithms to quantify the movement disorder symptoms. The predicate algorithm uses equations and thresholds, while the proposed algorithm was developed using machine learning. Although the algorithms are different, both devices provide similar quantification of the presence or absence of motor symptoms. In addition, the outputs of both devices indicate the presence of movement disorder symptoms (i.e., bradykinesia, tremor, and dyskinesia) in adult patients diagnosed with Parkinson's disease. The predicate device provides symptom scores every 2 minutes in median and percentiles which are compared to a control group with subjects with no Parkinson's disease. In comparison, NeuroRPM directly outputs the presence of 3 symptom types according to **Table 1**, without comparison to a control group. Although the output scales and references differ, NeuroRPM outputs were validated in a clinical trial, demonstrating that the device performance is adequate to support the intended use of quantifying movement disorder symptoms. Thus, these differences in technological characteristics do not raise different questions of safety and effectiveness.

Performance Bench Testing:

Bench testing was conducted to verify that the motion data from the Apple Watch reflected the subject's activities within the expected signal patterns and range of values, and that there were no outliers. Raw motion data from test subjects wearing Apple Watch were collected during UPDRS and AIMS evaluation and analyzed in time and frequency domains. The test results demonstrated that the motion data for all subjects were consistent and reliable.

Performance Clinical Testing:

An observational, non-intervention study in 36 subjects was conducted to evaluate NeuroRPM's ability to quantify Parkinson's symptom presence or absence. The primary endpoints for demonstrating the performance of the NeuroRPM symptom outputs were sensitivity and specificity. Subjects who were previously diagnosed with Parkinson's disease were enrolled in the study. Scores for each subject were obtained using validated clinical scales, the Unified Parkinson Disease Rating Scale (UPDRS) and the Abnormal Involuntary Movement Scale (AIMS). The ground truth for each sample was derived based on the majority score of an expert rater panel of 3 board-certified movement disorder specialists.

The summary of subject demographics is provided below and is from a single site with 95.5% Caucasian subjects.

Table 2 - Summary of Subject Demographics

Demographics	Min	Mean	Max
Age	46	67.7	85
Approx. Age at Diagnosis	35.1	59.8	81.3
Years Since Diagnosis	0.3	7.9	19
Average Total UPDRS-III Score	3.4	11.1	26.7
Number of Males	–	18	–
Number of Females	–	18	–

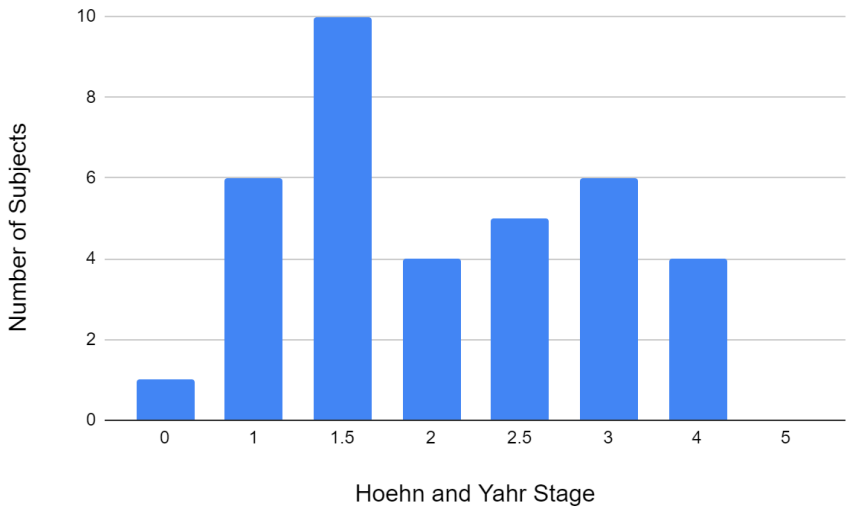

Figure 1 - Histogram of Hoehn and Yahr Stages (n=36)

The validation study was not specifically tested in the home environment; however, additional supportive data from the clinic, where subjects performed common at-home tasks and observed naturalistic behaviors, were provided to demonstrate the potential for similar performance in the home environment.

Clinical performance testing demonstrated that NeuroRPM is substantially equivalent to the predicate device. 95% confidence intervals were estimated based on the subject cluster bootstrap method.

Table 3 - NeuroRPM Output Sensitivity and Specificity of the event with 95% Confidence Intervals

NeuroRPM Output	Sensitivity [95% CI]	Specificity [95% CI]
Tremor	0.7176 [0.6081, 0.8172]	0.9508 [0.9119, 0.9802]
Bradykinesia	0.7143 [0.5894, 0.8332]	0.7740 [0.6787, 0.8597]
Dyskinesia	0.7123 [0.5323, 0.8652]	0.9466 [0.9069, 0.9741]

Sample size n = 36

The analysis is based on events instead of subjects. There are a total of 36 subjects who may have all the 3 types of events. The total number of events (from truth) for sensitivity evaluation is 170 for Tremor, and 203 for BK and 73 for DK. The number of events (from truth) for specificity evaluation is 325 for Tremor, 292 for BK, and 422 for DK.

Conclusions:

NeuroRPM is substantially equivalent to GKC's Personal Kinetigraph (PKG) System Model GKC-2000. NeuroRPM has the same intended use, technological characteristics, and principles of operation as the predicate device. The differences in indications for use do not introduce a new intended use. In addition, technological differences between NeuroRPM and the predicate device do not raise different questions of safety or effectiveness.

Substantial equivalence comparison of the predicate device and NeuroRPM is provided in **Table 2**.

Table 2 - Substantial Equivalence Comparison of Predicate Device and NeuroRPM

	Predicate Device: GKC PKG System (K161717)	**Subject Device: NeuroRPM**	**Comparison**
Indications for Use	The Personal Kinetigraph (PKG) is intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age.	NeuroRPM is intended to quantify movement disorder symptoms during wake periods in adult patients 46 to 85 years of age with Parkinson's disease. These symptoms include tremor, bradykinesia, and dyskinesia. NeuroRPM is intended for clinic and home environments.	Same intended use of quantifying movement disorder symptoms.
Wearable Device	Proprietary watch with accelerometer.	Apple Watch triaxial inertial measurement unit.	Both use wrist-worn devices to measure movement.
Algorithm	Equation with data in frequency domain.	Machine learning model with data in time and frequency domain.	Both algorithms are deterministic and generate classifications.
Symptom Measured	Tremor, bradykinesia and dyskinesia.	Tremor, bradykinesia, and dyskinesia.	Same symptom measurements. The subject device produces binary symptom outputs.
Outputs	Symptom measurement every 2 minutes in median and percentiles which are compared to a control group with subjects with no Parkison’s disease.	Symptom presence or absence levels every 15-minutes.	NeuroRPM provides direct symptom measurement without comparison to a control group. 15-minute intervals provide sufficient characterization of whether a symptom is present.
Output Report	PDF report with daily graphs and summary statistics of symptom outputs.	PDF report with daily graphs and summary statistics of symptom outputs.	Same output report formats with similar symptom information and visualizations.
Medication Reminder	Yes	No	Not required for quantification of movement disorder symptoms.