March 11, 2022

GKC Manufacturing Pty Ltd
% Kathy Herzog
Regulatory Consultant
DuVal & Associates, P.A.
Suite 1820, Medical Arts Building 825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K211887
Trade/Device Name: Personal Kinetigraph (PKG) System Gen 2 Plus
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor Transducer
Regulatory Class: Class II
Product Code: GYD, ISD, NXQ
Dated: February 8, 2022
Received: February 9, 2022

Dear Kathy Herzog:

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 801and Part 809; 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,

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)*

Device Name
Personal Kinetigraph (PKG) System - Gen 2 Plus

Indications for Use *(Describe)*
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.

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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5.0 510(K) SUMMARY

The 510(k) Summary has been prepared in accordance with Title 21 CFR Part 807 and is provided below.

5.1 Submitter

GKC Manufacturing Pty Ltd
Level 9, 31 Queen Street
Melbourne, Victoria 3000
Australia

Contact Person: Jim Quackenbush
Phone (USA): +1 612.819.5478
Email: jim.quackenbush@globalkineticscorp.com
Date Prepared: 17 June 2021

5.2 Device

Trade Name:	Personal Kinetigraph (PKG) System Gen 2 Plus
Common or Usual Name:	Movement Disorder Monitoring System
Classification Name:	Transducer, Tremor (21 CFR 882.1950)
Regulatory Class:	II
Product Codes:	GYD, ISD, NXQ

5.3 Predicate Device

Personal Kinetigraph (PKG) System Model GKC-2000 (Gen 2) (K161717).

The predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

5.4 Device Description

The Personal Kinetigraph (PKG) Gen 2 Plus utilizes a PKG Watch (movement data logger) worn by the patient on their wrist over 6-to-10 day recording cycles. The PKG Watch continuously records and quantifies the kinematics of movement disorder symptoms such as bradykinesia (BK), dyskinesia (DK), tremor, immobility, and dyskinesia fluctuations, in movement disorder conditions such as Parkinson's disease. Proprietary PKG Analysis Algorithms are used to analyze the movement data and generate a PKG-2A Report, which provides the clinical provider with a summary of these movement disorder symptoms, plotted over the full recording period. The PKG-2A Report includes an additional feature that allows the plots to be annotated by a qualified PKG Reporter.

The PKG Watch includes a medication reminder to notify the patient when it is time to take their medication, and an event marker for the patient to record when they have taken their prescribed medication. The Personal Kinetigraph (PKG) Gen 2 Plus System includes the GKCM Cloud Platform (PKG Clinic Server), a cloud-based service for receiving and processing the movement data files and generating PKG-2A Reports.

The Personal Kinetigraph (PKG) Gen 2 Plus is a modified version of the predicate Personal Kinetigraph (PKG) System Model GKC-2000 (Gen 2) cleared under K161717, incorporating several new or enhanced features, including a Docking Station for charging the PKG Watch and uploading movement data files to the GKCM Cloud Platform, and a Clinic Portal (housed in the GKCM Cloud Platform), providing customer facing functions such as creating and editing patient details, scheduling medication reminders, raising PKG orders and viewing the PKG-2A Report.

The Personal Kinetigraph (PKG) Gen 2 Plus also includes a PKG Tablet and PKG Dock Cable, cleared previously under K161717. The PKG Tablet is an off-the-shelf Android based tablet that runs a custom software application to configure the PKG Watch before a recording session, extract recorded data after a recording session, and upload this data to the GKCM Cloud Platform. The PKG Dock Cable connects the PKG Watch to the PKG Tablet for configuration before a recording session, and allows for uploading of the movement data to the PKG Clinic Server after the recording session. The PKG Tablet and PKG Dock Cable are not required when using the Docking Station and Clinic Portal.

The Personal Kinetigraph (PKG) Gen 2 Plus system consists of the following key components:

- PKG Watch (movement data logger) including wrist bands;
- PKG Docking Station;
- PKG Clinic Portal;
- GKCM Cloud Platform (PKG Clinic Server);
- PKG Analysis Algorithms;
- PKG-2A Report;
- PKG Tablet;
- PKG Dock Cable; and
- 5-Bay charger.

5.5 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.

5.6 Comparison of Technological Characteristics with the Predicate Device

The Personal Kinetigraph (PKG) System Gen 2 Plus is a modified version of the predicate Personal Kinetigraph (PKG) Model 2000 (Gen 2), cleared under K161717. The key changes to the PKG System reported in this application include:

- The introduction of a Docking Station for charging the PKG Watch and uploading data to the PKG Clinic Server.
- The introduction of the PKG Clinic Portal as an alternative to the PKG Tablet Application for use by the authorized Clinic staff to order PKGs, configure the PKG Watch, access PKG data, and manage all registered patients using the PKG Gen 2 Plus system at their clinic.
- Changes to the GKCM Cloud Platform to host the Clinic Portal, and web services required for communication with the Docking Station.
- Modifications to the PKG Report (PKG-2A), including annotations summarizing PKG findings performed by a qualified PKG Reporter, changes to the format and presentation of the graphical and tabular displays, addition of a longitudinal view of the previous 2 PKG report measures, and the inclusion of target ranges.
- Additional wrist strap options for the patient to wear the PKG watch.
- Additional validated PKG Tablet models.
- Modified packaging to accommodate the Docking Station.

5.7 Performance Data

The following performance data have been provided in support of the substantial equivalence determination:

5.7.1 Electrical Safety, Essential Performance and Electromagnetic Compatibility (EMC)

The changes introduced in the Personal Kinetigraph (PKG) - Gen 2 Plus underwent electrical safety and EMC evaluation and testing according to the following standards:

- IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

- IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. (Edition 1)

5.7.2 Mechanical Safety Testing

The changes introduced in the Personal Kinetigraph (PKG) - Gen 2 Plus underwent mechanical safety evaluation and testing in accordance with the applicable requirements of 60601-1:2005+A1:2012 and IEC 601-1-11:2015 (home healthcare environment). Testing included:

- Shock & Vibration;

- Continuous Operation (Thermal Cycling);

- Transport and Storage;

- Impact Testing;

- Ingress Protection (IP21);

- Drop testing;

- Push testing; and

- Molding Stress Relief;

5.7.3 Software Verification and Validation Testing

Software verification and validation testing were conducted in accordance with *IEC 62304:2006 + AMD1:2015 Medical device software — Software life cycle processes* and *FDA's Guidance for Industry* and *"FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005*.

5.7.4 Cybersecurity

The Personal Kinetigraph (PKG) - Gen 2 Plus was designed and developed in accordance with the applicable requirements outlined in the FDA guidance *Content of Premarket*

Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff OCTOBER 2018.

5.7.5 Biocompatibility Assessment

A biocompatibility evaluation for the Personal Kinetigraph (PKG) - Gen 2 Plus was conducted in accordance with the FDA Guidance document: *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process" September 4, 2020*.

The following testing was conducted on the modified Wrist Strap materials:

- ISO10993-5:2009 Cytotoxicity;
- ISO10993-10:2010 Sensitization; and
- ISO10993-10:2010 Irritation.

Biocompatibility testing was performed in an FDA recognized GLP testing facility.

5.7.6 Human Factors Engineering / Usability Testing

Usability testing and Human Factors Engineering (HFE) was performed during the design and development of the Personal Kinetigraph (PKG) - Gen 2 Plus in accordance with the applicable requirements of *IEC 62366-1:2015 Medical Devices: Part 1: Application of Usability Engineering to Medical Devices* and *FDA Guidance. Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff. February 3, 2016*.

5.7.7 Clinical Data

Clinical data was not required for this submission as the changes to the Personal Kinetigraph (PKG) - Gen 2 Plus did not introduce any significant new risks, or changes to known risks, that would require clinical evaluation.

5.8 Conclusions

The safety and bench test data demonstrated that the Personal Kinetigraph (PKG) - Gen 2 Plus is substantially equivalent to the predicate device PKG System Model GKC-2000 (Gen 2) for the same intended use.

Any differences between the Personal Kinetigraph (PKG) - Gen 2 Plus and the predicate version of the device are not significant and do not raise new or different questions of safety or effectiveness.