DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 20, 2016

Gkc Manufacturing Pty Ltd.
% Marie Schroeder
Advisory Services
Quintiles
1801 Rockville Pike Suite 300
Rockville, Maryland 20852

Re: K161717
Trade/Device Name: Personal Kinetigraph (PKG) System Model GKC-2000
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor Transducer
Regulatory Class: Class II
Product Code: GYD, NXQ, ISD
Dated: June 6, 2016
Received: June 22, 2016

Dear Marie Schroeder:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.09.20 16:37:38 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161717

Device Name

Personal Kinetigraph (PKG) System - Model: GKC-2000

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.

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510(k) Summary

5.1 SUBMITTER

GKC Manufacturing Pty Ltd
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Melbourne, Victoria, 3000,
Australia

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Email: brendan.fafiani@globalkineticscorp.com

Date Prepared: May 24, 2016

5.2 DEVICE

Trade Name: Personal Kinetigraph (PKG) System – Model GKC-2000 (Gen 2)

Common or Usual Name: Movement Disorder Monitoring System.

Classification Name: Transducer, Tremor (21 CFR 882.1950)

Regulatory Class: II

Primary Product Code: GYD, ISD, NXQ

5.3 PREDICATE DEVICE

K140086 - Global Kinetics Corporation's Personal Kinetigraph (PKG) System, the previous version of the same system that is the subject of this 510(k).

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

No reference devices were used in this submission.

5.4 DEVICE DESCRIPTION

The new Personal Kinetigraph (PKG) System, Model GKC-2000 (Gen 2), utilizes a small, wrist-worn data logging activity monitor (the PKG Watch) that continuously records and quantifies the kinematics of movement disorder

symptoms over a 6 to 10 day period in movement disorder conditions such as Parkinson's disease.
At the end of the recording period, the movement recording data is uploaded via a Tablet application at the supervising clinic, to a cloud-based server.
A report is produced using the recorded data that objectively distinguishes the movement patterns consistent with tremor, bradykinesia, dyskinesia and immobility. This information can be used by the clinician to assess the extent and severity of movement disorder symptoms, and how they vary throughout the day, and from day to day.
The PKG Watch has a medication reminder to indicate to the patient that it is time to take their medication, and an event marker for the patient to record when they have taken their prescribed medication. (See **Figure 1** for system overview diagram.)

The Personal Kinetigraph (PKG) System, Model GKC-2000 (Gen 2), is an updated version of the predicate device, the Personal Kinetigraph System (PKG), which was cleared under K140086. While this new PKG System, Gen 2, has some design updates, the Indications for Use are identical to those of the predicate system (K140086).

The Personal Kinetigraph (PKG) System, Gen 2, consists of:

- The PKG Watch (movement data logger)
- The PKG Tablet
- The PKG Clinic Server
- The PKG PDF report, and
- The PKG Accessories.

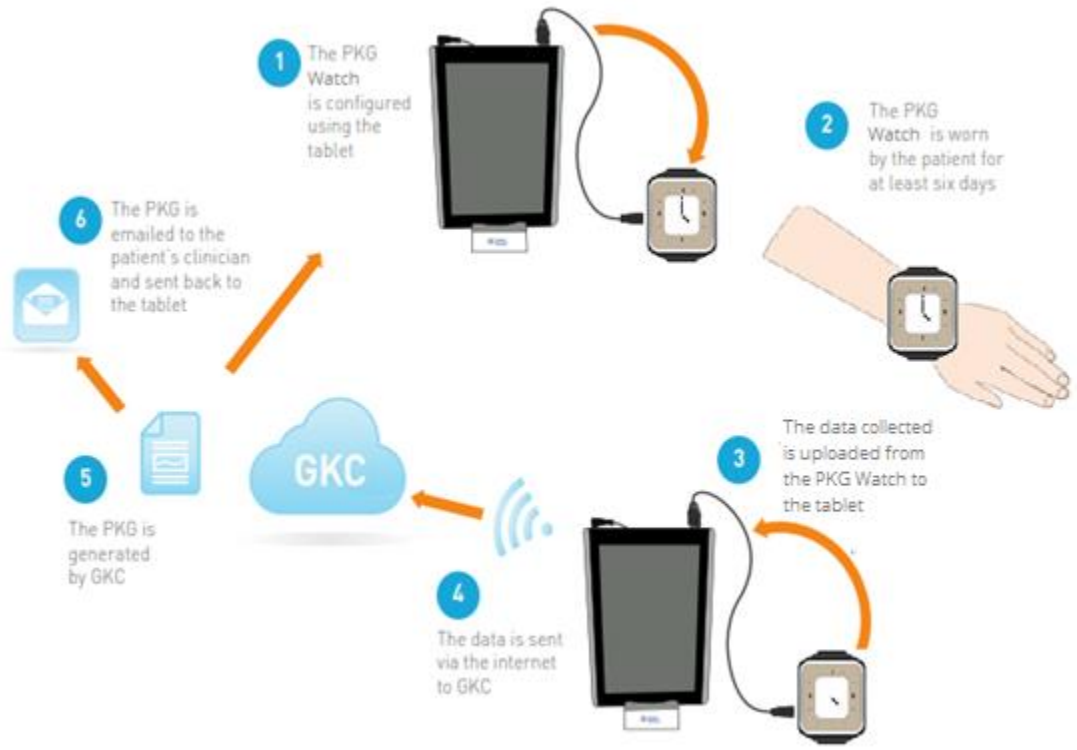

Figure 1 - PKG Gen 2 System components and operation overview

The PKG Watch is a battery powered, microprocessor device containing hardware and software that records the movements of a patient with movement disorders such as Parkinson's disease. It is a compact wrist worn monitor that records the patient's movements throughout the day over multiple days. These movement records are then sent via the Internet to the Global Kinetics Corporation (GKC) cloud-based server where they are analyzed to distinguish the movement patterns of the patient throughout the day and to indicate compliance with their medications.

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 PKG Clinic Server.

The PKG Clinic Server is a cloud-based service, which receives the movement data files from the PKG Tablet, and then processes the files using the PKG Analysis Software. This results in a number of graphs that summarize the content of the recorded data, for use by the clinician. These graphs and some ancillary data are presented in the PKG PDF Report. The PKG Clinic Server sends the PKG PDF Report automatically back to the clinic by email, as well as a copy back to the originating PKG Tablet in the clinic.

The PKG PDF report includes graphs showing the Bradykinesia Score (BKS), representative of bradykinesia, and Dyskinesia Score (DKS), representative of

dyskinesia, throughout the day on a time-of-day basis. Summary statistics are included to indicate the percentage of time spent at various levels of severity of BKS and DKS. The levels of severity are based on levels that exceed the specified percentile of recordings from normal control subjects. The clinician can use data in the PKG PDF report, together with other information, to adjust the patient's medications so that they spend more time in a normal movement state.

The PKG Accessories include:

- **The 5-Bay charger** - for charging the PKG Watch units, up to 5 at a time. Includes a mains USB adaptor and USB cable.
- **The PKG Dock Cable** – for connecting the PKG Watch to the PKG Tablet for configuration before a recording session, and for uploading the movement data to the PKG Clinic Server after the recording session.

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.

Note: The Indications for Use statement for the PKG Model GKC-2000 (Gen 2) is identical to the predicate, which is the previous version of the same system.

5.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The key operating principle of the system (as with the predicate) continues to be movement recording of the patient over a 6-10 day period and processing of the resulting recording in order to provide the PKG PDF report to the clinician.

The substantive changes to the PKG System that are being reported in this application relate to the design update of the PKG Logger in the predicate into the PKG Watch, and the related software changes in the Tablet Software in order to support the new PKG Watch data format. There are other changes relating to the size and type of charger supplied, but these are functionally equivalent to the predicate system - all other system performance parameters remain unchanged. All changes are limited to those necessary to implement the updated PKG Watch. The Indications for Use are identical to those cleared for the predicate PKG System.

At a high level, the new system and the predicate are based on the following same technological elements:

- PKG Tablet and Tablet Software workflow.
- PKG Clinic Server.
- PKG PDF reports.
- PKG Watch:
    - Data recording functions are unchanged.
    - Colored LED indicators (Orange / Green) are the same and retain the same meaning.
    - Vibrating medication alert remains unchanged – uses the same meanings and alert patterns.
    - Charged using a new charger, but the underlying technology is the same.
    - Configured using a different connecting cable to the PKG Tablet, but the underlying technology is the same.

The following technological differences exist between the new and predicate systems:

- PKG Tablet software – one minor change to support revised data transfer format for the new PKG Watch. (Unchanged otherwise)
- PKG Watch:
    - Now has a touch screen display, with clock display
    - Adds a Battery recharge indicator
    - Revised Strap and Enclosure design - now waterproof
    - Supplementary indicator symbol on display for medication reminder (‘Pill’ icon.)
    - Supplementary indicator symbol on display for medication acknowledgement (‘Tick’ icon.)

5.7 PERFORMANCE DATA

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

5.7.1 Biocompatibility Testing

The biocompatibility evaluation for the PKG Gen 2 System was conducted in accordance with the following FDA Guidance documents:

- FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995.
- FDA Draft Guidance: Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing" Within a Risk Management Process," April 23, 2013.

The battery of testing included the following tests:

- ISO10993-5 Cytotoxicity
- ISO10993-10 Dermal Irritation
- ISO10993-10 Sensitization

The testing was performed by CPTC, an FDA recognized GLP testing facility – with all protocols and reports conforming to GLP.

The key component tested was the PKG Watch, which is a wrist worn, surface device that contacts intact skin and has a contact duration of >24 hours and ≤ 30 days.

The samples supplied to CPTC labs for biocompatibility testing were all in their final finished form: production-molded parts, using the final manufacturing process parameters, and that had been colored according to their design specifications.

All results demonstrated that there were no adverse or unexplained events and that there were no indications for cytotoxicity, irritation and sensitization. As such these materials pose a low risk for the purpose of surface application on intact skin for the specified contact duration of less than 30 days. In this context, the materials can be considered to have met the biocompatibility requirements for safety for use in the PKG2 System.

5.7.2 Electrical Safety and electromagnetic compatibility (EMC)

An electrical safety and EMC evaluation was performed for the PKG Gen 2 System, which included Electrical and EMC testing on the system components including the PKG Watch, the 5-Bay Charger and the PKG Dock Cable. The system complies with the following standards:

IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. (Edition 3)

IEC 60601-1-11:2010 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)

IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (Edition 3)

IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. (Edition 4 – selected tests were performed from this standard.)

IEC 62133:2012 - Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

5.7.3 Mechanical Safety Testing

The PKG Watch underwent mechanical safety testing in accordance with the mechanical safety requirements of IEC 60601-1:2005.

Tests were performed for:

- Push Testing
- Drop Testing
- Mold Stress Relief
- Altitude Testing
- Thermal Cycle Testing
- Shock Testing
- Broad-band Random Vibration Testing
- Ingress Protection Testing.

The PKG Watch complied with all tests.

5.7.4 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005.

The software for the PKG Gen 2 System was considered as a "moderate" level of concern, since a failure or latent flaw in the software could result in a Minor injury to the patient in some situations.

5.7.5 System Validation testing

The specifications and performance of these key sections of the system have not changed significantly for the PKG Gen 2 System update:

- Movement recording
- Medication reminders
- Medication acknowledgement
- PKG Analysis and PKG PDF report

These sections of the system are the key areas that may require use of new clinical data to re-validate them in the case that they were modified significantly.

As none of these have changed significantly, re-validation of the PKG Gen 2 System relied upon both bench verification of the new system, as well as side-by-side validation of the new system with the predicate, when worn by test subjects. Further clinical validation was not considered necessary.

A review of all system verification testing that had been performed was undertaken. This included system verification testing; external safety testing; testing of the system with key use cases on users; and the evaluation of system ergonomics; as well as common fault testing and Clinic Software Validation.

As the final level of validation, system performance testing was undertaken for the PKG Gen 2 System against the predicate system. This exercise included the side-by-side analysis of the PKG Watch for Gen 2 and the PKG Logger for the predicate and subsequent analysis and comparison of the PKG PDF Reports generated. The primary aim of this exercise was to prove performance equivalence between the two systems.

The test was conducted over several days, with each of the test subjects wearing two recording loggers simultaneously on the same arm (PKG Watch and/or the predicate Data logger), performing predetermined actions and maintaining a diary. The PKG PDF Reports that resulted from each device were compared to determine any changes in system performance.

In summary the data and results from this side-by-side comparative testing show that the functional performance of the PKG Gen 2 System is identical to the predicate system (within the specified acceptance criteria of system variability) for all measures, with the exception of accidental ‘medication taken’ acknowledgements, where the PKG Gen 2 System is improved over that of the predicate.

5.8 CONCLUSIONS

Although the predicate device was cleared based in part on clinical studies, based on our risk analysis, there have not been changes to the new PKG System (Gen 2) that require clinical revalidation. Therefore clinical testing was not required to support substantial equivalence.

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the PKG System (Gen 2) should perform as intended in the specified use conditions.

The safety and bench test data demonstrate that the PKG System (Gen 2) performs comparably to the predicate that is currently marketed for the same intended use. Therefore the PKG System (Gen 2) is substantially equivalent.