November 22, 2018

Neuro Kinetics, Inc.
Brian Sullivan, COO
128 Gamma Drive
Blawnox, PA 15238

Re: K171884
Trade/Device Name: I-Portal® Portable Assessment System™ - Nystagmograph (I-PAS™)
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: October 19, 2017
Received: October 23, 2017

Dear Brian Sullivan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*

K171884

Device Name
I-Portal® Portable Assessment System™ - Nystagmograph (I-PAS™)

Indications for Use *(Describe)*
I-Portal® Portable Assessment System™ - Nystagmograph (I-PAS™) is used in vestibular and neuro otologic diagnostic testing. The I-PAS provides stimuli to a patient through visual cues, monitors the patient's response, and presents the data for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device does not provide diagnoses nor does it provide diagnostic recommendations.

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

NKI's I-PAS™

Submitter

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Date Prepared: June 20, 2017

Trade/Proprietary Name: I-Portal® Portable Assessment System™ Nystagmograph (I-PAS™)

Common Name: Nystagmograph

Classification Name: Nystagmograph (21 CFR 882.1460, Product Code GWN)

Predicate Device: I-Portal® VNG (K083603 & K143607)

Device Description

All I-Portal® devices, including the proposed I-PAS, function as nystagmographs, defined by 21 CFR 882.1460 as "a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball." Through its nystagmograph functionality, the I-PAS is indicated for use as a diagnostic tool to assist trained physicians in their analysis of vestibular and neurotologic disorders, requiring a separation of central and peripheral nervous system deficits. The I-PAS and all other I-Portal devices are used in an institutional environment on the order of a physician.

The I-Portal devices use a battery of oculomotor and vestibular tests across a family of products: including the I-Portal NOTC, I-Portal VNG, and I-Portal VOG. This application seeks to add I-PAS to this family. The VNG testing battery included on the I-PAS and other I-Portal devices include ten (10) oculomotor and subjective visual tests.

The I-PAS is a head-mounted apparatus enclosing a digital display, infrared lights, dual mirrors, dual cameras, and optical focus knobs. It is attached to the head with straps. The head mounted goggle system displays independent stimuli separately to each eye on a small digital display while simultaneously recording motion from each eye independently with digital video cameras. The system also includes: a computer with Neuro Kinetics' I-Portal and VEST software packages; isolation transformer and connection cables; foot pedals and a hand-held control box with buttons that can be pressed to register motor responses. As with the I-Portal VNG, I-PAS includes the standard battery of VNG tests and can operate in conjunction with caloric test equipment.

Intended Use / Indications for Use

The modified I-Portal has the same intended use and indications for use as the predicate cleared per K083603 & K143607. Both the I-PAS and its predicate device are intended for use as a nystagmograph. The indications for use for the modified I-Portal device and the predicate device cleared per K083603 & K143607 are identical, and are as follows:

I-PAS™

I-Portal® Portable Assessment System Nystagmograph (I-PAS) is used in vestibular and neuro otologic diagnostic testing. The I-PAS provides stimuli to a patient through visual cues, monitors the patient's response, and presents the data for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations.

Technological Characteristics

The I-PAS has identical technological characteristics as the previously cleared predicate (K083603 & K143607), with the exception of the following modifications:

Integrated head mounted display/monitor inches from the eyes replacing projection devices /monitors that display visual cues on a surface at a distance of feet.

A small screen or monitor (smart phone display) is divided into two halves, each providing visual cue(s) to a single eye displayed approximately 3 inches from each eye in the head mounted screen that create a perceived distance, or digital equivalents that subtend the same location, angles, and speeds of the visual stimuli, i.e., dots. The visual cues are functionally equivalent to predicate visual cues projected by the pursuit tracker laser and optokinetic (OKN) on to a surface between 2 to 3 feet away from the subject. The embedded optics of the I-PAS are also adjustable to optimize the image for patients whose eyes require a prescription, since it is not possible to wear eyeglasses while wearing I-PAS.

Fully enclosed unit that keeps out ambient light

Unlike the predicate, I-PAS is portable and the stimulus presentation and eye tracking are completely self-contained within the head mounted system. The same light seal gasket used for all I-Portal devices provides a test environment without ambient light. The predicate device projects stimuli on a wall in a dark room while the subject viewed the stimuli while wearing eye-tracking goggles.

Use of 6DOF sensor to provide head position measurements during vestibular tests, e.g. Subjective Visual tests

The I-PAS includes a 6DOF sensor to help make I-PAS portable. A patient's head may not always be stationary, i.e.. secured in a headrest. As a result, if the patient tilts their head away from earth vertical, tests such as the subjective visual tests can generate inaccurate results. The 6DOF provides an accurate measure of head and stimulus orientation to either enable the tester to orient the patient's head correctly, and or for a comparison of subjective visual results to earth ground.

The clinical testing performed confirms that the visual cues are functionally indistinguishable from the predicate, and that I-PAS stimuli do not cause dizziness. Additionally, bench testing confirms that the I-PAS complies with ANSI-ASA S3.45-2009 and verification and validation testing demonstrate that users can safely and effectively use the I-PAS.

Non-Clinical and Clinical Performance Data

Both bench and clinical testing provide significant support for this application.

Bench tests were executed to verify and validate the I-PAS, and to demonstrate its conformance with ANSI-ASA S3.45-2009, FDA's applicable consensus standard.

Compliance with applicable IEC 60601 standards is confirmed via 3rd party testing.

Verification testing consisted of verification of the software requirements and hardware requirements.

Validation testing was performed to ensure that users were able to properly use I-PAS and that the user interface was operating as intended.

The verification and validation test results confirm that the I-PAS performs as intended.

Clinical studies were also run and confirmed that the I-PAS visual cues are functionally indistinguishable from the predicate visual cues and that I-PAS stimuli do not cause dizziness.

Substantial Equivalence

The I-PAS is substantially equivalent to its predicate. It has the same intended use, the same indications for use and equivalent technological and equivalent clinical characteristics and equivalent principles of operation. The technological differences do not present any new issues of safety or effectiveness, which is supported by performance data.

The I-PAS is substantially equivalent to its predicate (K083603 & K143607) device.