July 24, 2018

Neuro Kinetics, Inc.
Robin C. Ashmore
Biomedical Software Engineer
128 Gamma Drive
Pittsburgh, PA 15238

Re: K181025
Trade/Device Name: I-Portal Neuro Otologic Test Center; I-Portal Video Nystagmography System; I-Portal Video Oculography Eye Tracking System
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: April 13, 2018
Received: April 18, 2018

Dear Robin Ashmore:

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 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,

Srinivas Nandkumar -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181025

Device Name

I-Portal® Neuro Otologic Test Center (NOTC)

Indications for Use *(Describe)*

I-Portal® Neuro Otologic Test Center (NOTC) is a rotary chair system used in vestibular and neuro-otologic diagnostic testing. The NOTC provides stimuli to a patient through motion profiles and/or 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on April 13th 2018.

I. Submitter

Submitter's Name:	Neuro Kinetics, Inc.
Contact Person:	Mr. Robin C. Ashmore, PhD Biomedical Software Engineer
Address:	128 Gamma Dr. Pittsburgh, PA 15238
Telephone:	(412) 963-6649
Fax:	(412) 963-6722
Email:	rashmore@neuro-kinetics.com

II. Device

Trade Name	Proprietary Name
• I-Portal® Neuro Otologic Test Center (NOTC)	• I-Portal® Neuro Otologic Test Center (NOTC)
• I-Portal® Video Nystagmography System (VNG)	• I-Portal® Super VNG System 1 (SVNG-1) • I-Portal® Super VNG System 2 (SVNG-2)
• I-Portal® Video Oculography Eye Tracking System (VOG)	• I-Portal® Falcon™ VOG (SVNG-3)

Common/Usual Name:	Nystagmograph
Classification Name:	Nystagmograph
Product Classification:	Class II, § 882.1460, Product Code GWN

III. Predicate Device

- Neuro Kinetics Inc.'s I-Portal® NOTC, VNG and VOG
    - K143607 (I-Portal® NOTC, VNG and VOG), FDA cleared on 07/08/2015

IV. Device Description

The I-Portal device functions as a nystagmograph, 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 device is indicated for use as a diagnostic

tool to assist trained physicians in their analysis of vestibular disorders, which requires the separation of central and peripheral nervous system deficits. The I-Portal device is used in an institutional environment on the order of a clinician.

To achieve safe and effective clinical operation, the I-Portal devices use an extensive battery of tests within a family of products: the I-Portal NOTC, the VNG, and the VOG.

The I-Portal NOTC features a rotational chair, the optokinetics (OKN) optical stimulus, the Pursuit Tracker (PT) laser target generator, an I-Portal VOG, I-Portal and VEST software, and a test enclosure equipped with a communication system. Through the use of these elements and the VEST™ analysis software, the physician is able to schedule a set of tests designed to help isolate, identify and understand oculomotor, neurologic and vestibular functions and related possible disorders.

The I-Portal VNG offers a subset of the NOTC tests and different vestibular tests through a device with a smaller physical footprint. The VNG has many of the same elements used in the NOTC configuration: OKN optical stimulus, PT laser target generator, VOG, I-Portal and VEST software platforms. However, unlike the NOTC, it does not have either the rotational chair or the enclosure & communication system, but the VNG can collect and analyze data from caloric and position tests. The VNG configuration is typically used in smaller clinics or conditions requiring a smaller sized device or some mobility.

The third NKI I-Portal configuration is a digital eye tracking system – the I-Portal VOG. The VOG is incorporated within the NOTC and VNG configurations; however, the VOG can be used as a stand-alone product with the VEST and I-Portal software, but offering a subset of the tests afforded by either the NOTC or VNG.

V. Indications for Use

NOTC

I-Portal® Neuro Otologic Test Center (NOTC) is a rotary chair system used in vestibular and neuro-otologic diagnostic testing. The NOTC provides stimuli to a patient through motion profiles and/or 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.

VNG

I-Portal® Video-Nystagmography System (VNG) is used in vestibular and neuro otologic diagnostic testing. The VNG 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.

VOG

I-Portal® Video Oculography (VOG) System is used to monitor and record eye movements from various stimuli used in vestibular diagnostic testing. The system measures and records horizontal, vertical, and torsional eye movements, as well as pupil area. It is used in conjunction with various stimuli (rotary chair, manual (done by clinician) positional maneuvers, caloric tests, external stimulus) to detect and record nystagmus and eye tracings for interpretation by qualified

medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations.

VI. Comparison of Technological Characteristics with the Predicate Devices

The modified I-Portal® devices have identical technological characteristics as the I-Portal® NOTC, VNG and VOG (K143607), with the exception of the following modifications:

I-Portal VOG Goggle Camera and Connection Type
The I-Portal® VOG cameras and connection point for the I-Portal® NOTC, VNG and VOG devices were updated to include a VOG-B250 goggle (USB3, also known as the "I-Portal® Falcon™") with a camera connected via USB connection in addition to the current VOG-B100 (IEEE-1394) camera connected via FireWire port.

VEST™ Software Modification

Neuro Kinetics Inc.'s VEST™ software was upgraded to version 8.0.2. This version of the VEST software includes various improvements to the programming workflow for improved productivity and an enhanced user interface for operator convenience and efficiency. The enhanced user interface includes additional prompts and visual indications when executing the testing program, and improved default parameter settings during analysis.

I-Portal® Software Modification

Neuro Kinetics Inc.'s I-Portal® software was upgraded to version 6.0. This version of I-Portal® Software improves video capture (250+ frames per second) and pupil detection. Modifications include:

- Enhanced pupil detection using an auto threshold feature

VII. Performance Data

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

Performance Standards

ANSI S3.45-2009 (Reaffirmed 2014), *American National Standard Procedures for Testing Basic Vestibular Function*.

Software Verification and Validation Testing

Testing was conducted to verify the I-Portal® NOTC, VNG and VOG modifications. Verification testing consisted of verification of the software and hardware modifications. System usability validation (with defined and documented Use Cases) was performed at multiple VEST software revision levels. The results of the testing met the acceptance criteria and did not identify any new unforeseen risks. Therefore, the I-Portal® NOTC, VNG and VOG devices continue to be safe and effective for their intended use

Risk Analysis

The results of the device hazard analysis did not identify any unacceptable residual risks nor increase to the overall device risk profile as they were originally cleared on 07/08/2015 (K143607).

VIII. Conclusion

The information provided in this submission supports safety and effectiveness of the modified I-Portal® NOTC, VNG and VOG devices for their intended use and demonstrates that the devices are substantially equivalent to their predicate.