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

July 8, 2015

Neuro Kinetics, Inc.
Mr. J. Howison Schroeder
President and CEO
128 Gamma Drive
Pittsburgh, PA 15238

Re: K143607
Trade/Device Name: I-Portal Neuro Otologic Test Center (NOTC), I-Portal Video Nystagmography System (VNG), and I-Portal Video Oculography Eye Tracking System (VOG)
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: June 5, 2015
Received: June 5, 2015

Dear Mr. 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 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)*

Device Name

I-Portal® Neuro Otologic Test Center (NOTC), N/A; I-Portal® Video Nystagmography System (VNG), N/A; I-Portal® Video Oculography Eye Tracking System (VOG), N/A

Indications for Use *(Describe)*

I-Portal® Neuro Otologic Test Center (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.

I-Portal® Video-Nystagmography System (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.

I-Portal® Video Oculography (VOG) System

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.

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

Submitter J. Howison Schroeder
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Phone: (412) 963-6649
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Date Prepared: December 18, 2014

Trade/Proprietary Name: I-Portal® Neuro Otologic Test Center (NOTC)
I-Portal® Video Nystagmography System (VNG)
I-Portal® Video Oculography Eye Tracking System (VOG)

Common Name: Nystagmograph

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

Predicate Device

I-Portal® NOTC, I-Portal® VNG, I-Portal® 4D VOG System (K083603)

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 is used in an institutional environment on the order of a physician.

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

The I-Portal NOTC features a rotational chair, the OKN optical stimulus, the PT laser target generator, the I-Portal VOG, 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 isolating oculomotor and vestibular functions to help the physician understand possible vestibular 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: the OKN optical stimulus, the PT laser target generator, the VOG, and the VEST

software platform. However, unlike the NOTC, it does not have the rotational chair, and does not utilize 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 device mobility.

The third configuration of the NKI I-Portal 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 software, but offering a subset of the tests afforded by either the NOTC or VNG.

Intended Use / Indications for Use

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

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.

Technological Characteristics

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

User-defined normative data input and display
The addition of user-defined normative data input and display does not alter the raw data or analysis results gathered from the patient. In current clinical practice, users may store normative data ranges in various locations (separate electronic files, written notes) or they may rely solely on their clinical judgment. This feature provides the user with a safe and convenient storage location for this information, as well as a way to easily analyze patient results with respect to the clinician's choice of normal values. By providing this feature, the software will eliminate the need to draw the normal areas by hand on screenshot printouts of every patient graph. Validation testing has been conducted to demonstrate that users can safely and effectively use the I-Portal with user-defined normative data input.

Controlled rotation Head Impulse Test (crHIT)
The crHIT test is a high acceleration inter aural rotation test performed in the I-Portal NOTC chair to examine the high-frequency properties of the peripheral vestibular system. The crHIT test is substantially equivalent to the head thrust test, previously cleared for the predicate device, as both tests collect similar data, include similar calculations, and provide similar outputs. Verification testing confirmed that hardware modifications do not impact the functionality of the I-Portal. Therefore, the addition of crHIT does not raise new questions of safety or effectiveness.

Performance Data

Bench tests were executed to verify and validate the I-Portal. 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 the I-Portal and that the user interface was operating as intended. Clinical testing was also performed to evaluate the crHIT test outputs for 22 control subjects and 20 subjects with complaints of dizziness to demonstrate the equivalence of the test outputs between the crHIT test and the head thrust test. The verification and validation test results confirm that the I-Portal performs as intended.

Substantial Equivalence

The modified I-Portal and its predicate device cleared per K083603 have the same intended use and indications for use and similar technological characteristics and principles of operation. The technological differences do not change the intended use or present any new issues of safety or effectiveness. Performance data demonstrate that the modified I-Portal is as safe and effective as its predicate device. Thus, the modified I-Portal is substantially equivalent to its predicate device.