DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993-0002

Neuro Kinetics, Inc.
c/o Mr. Joe Argyros
Vice-President
128 Gamma Drive
Pittsburgh, PA 15238-2920

AUG 0 6 2009

Re: K083603
Trade/Device Name: I-Portal 4D Video Oculography Eye Tracking System (VOG), I-Porta
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: II
Product Code: GWN
Dated: June 16, 2009
Received: June 17, 2009

Dear Mr. Argyros:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statements

Indications for Use
510(k) Number: k063603
Device Name: I-Portal® Neuro Otologic Test Center (NOTC)
Indications for Use:

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.

Contraindications (if applicable):

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number k063603

4.0 Indications for Use Statements

Indications for Use Statements

Indications for Use
510(k) Number: K083603
Device Name: I-Portal® 4D Video Oculography (VOG) System
Indications for Use:

I-Portal® 4D 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.

Contraindications (if applicable):

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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510(k) Number K083603

Indications for Use Statements

Indications for Use
510(k) Number: K083603
Device Name: I-Portal® Video Nystagmography System (VNG)
Indications for Use:

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.

Contraindications (if applicable):

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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510(k) Number K083603