

## 2 510(k) Summary

Submitter: VeriSci Corporation  
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 Raritan, New Jersey 08869-1514  
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Contact Person: George Hu, Ph.D.  
 CEO

Trade Name: Neucodia

Classification Name: Stimulator, Photic, Evoked Response  
 Regulation Number: 882.1890  
 Classification Product Code: GWE

Regulatory Class: II

### 2.1 Identification of Legally Marketed Predicate Devices

The Neucodia system is substantially equivalent to Roland Consult's RETI-Port-Scan (K023525) and LACE Elettronica's GLAID Ocular Electrophysiology Device (K043367). The Neucodia device features are substantially equivalent to the predicate devices with respect to the device's general design concept, operational procedure, data processing methodology, data acquisition conditions, and indications for use. All the devices are electrophysiological (EEG) test systems that consist of electrical hardware and software to produce visual stimuli, EEG signal recording and processing for extraction of visual evoked potentials (VEPs). All the devices are intended to be used by trained medical professionals for the study of central visual functions.

### 2.2 Device Description

Visual stimuli are presented to the patient on the stimulus monitor. Visual evoked potentials are extracted from EEG epochs recorded via medical-rated EEG electrodes (not included in the device) attached to the scalp of the patient. Once the recording is complete, the digitized EEG data are processed by the software algorithm for noise filtering, artifact rejection, frequency and time domain analysis. The results are displayed on the user's monitor: EEG epochs, spectrum, Fourier components, and statistical measures (e.g., means, deviations, and signal to noise ratio).

### 2.3 Indications for Use

The Neucodia system is an electrophysiological device that generates photic stimuli, and records, processes and analyzes the resultant visual evoked potential (VEP) signals for the study of central visual functions

**2.4 Substantial Equivalence**

Product Name	Predicate Devices		Submission Device
	Roland Consult RET1-Port-Scan (K023525)	LACE Elettronica GLAID Ocular (K043367).	VeriSci Neucodia
<b>Indications for use</b> Electrophysiological device that measures and processes electroencephalographic signals elicited by visual stimuli presented on electronic display for the study of visual function	Yes	Yes	Yes
<b>Intended users</b> Vision researchers, neurologists, eye-care professionals, and trained medical technicians	Yes	Yes	Yes
<b>Intended population</b> Normal observers, individuals at-risk for visual pathway dysfunction or with confirmed ophthalmic disorders	Yes	Yes	Yes
<b>Site of use</b> Hospital, clinics, physicians' offices, and research laboratories	Yes	Yes	Yes
<b>Data collected</b> EEG signals	Yes	Yes	Yes
<b>Stimuli</b> Patterns on screen displayed in periodical functions	Yes	Yes	Yes
<b>Data processing</b> Frequency domain and time domain analysis, statistical analysis	Yes	Yes	Yes
<b>Hardware for signal amplification and AD converting</b> (Filter bandwidth, sampling rate, AD converting accuracy, Gain, CMRR, input impedance, input/output voltage range)	Yes	Yes	Yes
Conforms ISCEV standard			

**2.5 Performance and Validation**

Software: Verification and validation

Safety test: UL 60601-1, IEC 60601-2-26, EN60601-1-2, ISO15004-2

System: Bench testing for power supply requirement, amplifier gain and CMRR

Clinical testing:

VEP multi-variable statistics and signal to noise ratio were measured to produce system repeatability and reproducibility. 10 repeated sequential tests were performed on each subject to obtain repeatability performance data. In addition, each subject had three visits for the same repeated tests using different devices and with different operators and reapplication of electrodes to obtain reproducibility performance data. The clinical test results are described in Section 4.2.18, User's Manual and Section 5.2.3, Device Description.



MAY 15 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

VeriSci Corporation  
% George Hu, Ph.D.  
106 Anderson Street  
Raritan, New Jersey 08869

Re: K081591

Trade/Device Name: NEUCODIA  
Regulation Number: 21 CFR 882.1890  
Regulation Name: Evoked response photic stimulator  
Regulatory Class: II  
Product Code: GWE  
Datcd: April 24, 2009  
Received: April 29, 2009

Dear Dr. Hu:

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 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K081591

**1 Indications for Use**

Device Name: NEUCODIA

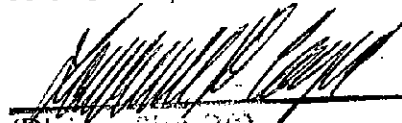
**Indications for Use:**

The Neucodia system is an electrophysiological device that generates photic stimuli, and records, processes and analyzes the resultant visual evoked potential (VEP) signals for the study of central visual functions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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