510(k) Summary

October 14, 2010

MAY - 9 2011

Device Description

Trade Name:	Diopsys™ NOVA VEP Vision Testing System
Common Name:	VEP vision testing system
Classification Name:	Evoked response photic stimulator
Regulation Number:	882.1890
Product Code:	GWE
Regulatory Class:	II

Contact Information

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Identification of Legally Marketed Predicate Devices

The Diopsys NOVA VEP Vision Testing System (NOVA), is substantially equivalent to the Diopsys Enfant® Pediatric VEP Vision Testing System (K043491) and the VeriSci Corporation Neucodia System (K081591). The NOVA device is substantially equivalent to the predicate devices with regard to device features, designs, operational procedure, data acquisition conditions, specifications, as well as intended use. All devices are visual evoked response test systems with similar operating requirements that are based on standard clinical procedures. These devices consist of hardware and software to provide photic stimulus and EEG capture and analysis of the evoked response. All the devices are intended to be used by trained medical professionals for the study of visual functions.

Device Description

Checkerboard, Horizontal grating, Vertical grating, Sinusoidal grating, Flash, monochromatic pattern onset or color pattern onset Contrast Photic stimuli are presented to the patient on a calibrated computer monitor at various numbers of elements in separately stimulated fields. The fields are varied in spatial size over a number of cycles. The fields are also phase reversed at different temporal frequencies. The signals are analyzed by the software algorithm for spatial/temporal filtering and artifact rejection. Data may be presented in numerical and graphical form. The device also utilizes attention grabbing features specifically for children or non attentive adults. In particular, a picture is presented prior to the onset of the VEP pattern

stimulus. During the picture presentation no data is collected. Age appropriate music is also available to patient as well. The music is only intended as an attention facilitator. From a hardware standpoint the NOVA system is identical to that of the Enfant, ® which was cleared under K043491. The only difference between the two devices is the software.

Indications for Use

The NOVA is an electrophysiological device that generates photic stimuli, and records, processes and analyzes the resultant visual evoked potential (VEP) signals to provide information about the visual system structural and neural abnormalities.

Comparison to Cleared Devices

Parameter	Diopsys NOVA	Enfant K043491	Neucodia K081591
Indications for Use	The NOVA is an electrophysiological device that generates photic stimuli, and records, processes and analyzes the resultant visual evoked potential (VEP) signals to provide information about visual system structural and neural abnormalities.	The Enfant is an is a non invasive medical device to screen without dilation or sedation, for visual disorders in infants and pre school children. The system uses visual evoked potentials to provide information about the visual pathway function and about optical or neural abnormalities related to vision.	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.
Target Population	Infants, pre-school children, children and adults	Infants and pre-school children	Normal observers, individuals at-risk for visual pathway dysfunction or with confirmed ophthalmic disorders
Where used	Hospitals, Clinics and physician offices	Hospitals, Clinics and physician offices	Hospitals, clinics, physicians' offices and research laboratories
Intended Users	Physicians and trained medical technicians	Physicians and trained medical technicians	Vision researchers, neurologists, eye-care professionals, and trained medical technicians
Energy Used	110V	110V	110V
Design	Synchronized Data Collection (external module), Transient VEP	Synchronized Data Collection, (internal module), Steady State VEP	Synchronized Data Collection, Steady State and Transient VEP
Electrical safety Standards met	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-26 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-26 IEC 60601-2-40	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-2-26 ISO 15004-2
Data Collected	EEG signals	EEG signals	EEG signals

Performance Data

Software: Verification and Validation

1). User Interface – User interface operates as expected.
2). Software Installation Process – Software installs as expected.
3). Signal Test Procedure – VEP recordings are displayed as expected.
4). System Configuration – Software configures hardware components as expected.
5). Calibration Test – Verifies VEP stimulus parameters meet specification.
6). Comparison of EEG Response – Verifies VEP recording compared to known recording.

Safety Testing: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-26, IEC 60601-2-40

System Testing: Bench testing for the system, EEG Amplifier and LCD.

Conclusion

The NOVA is substantially equivalent to the predicate Enfant and Neucodia based on safety and efficacy testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medqra, LLC
c/o Mr. Richard Hettenbach
President
44 Countrywood Drive
Morris Plains, NJ 07950

MAY - 9 2011

Re: K101763
Trade/Device Name: Diopsys™ NOVA VEP Vision Testing System
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: October 14, 2010
Received: October 18, 2010

Dear Mr. Hettenbach:

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 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

510(k) Number (if known): K101763

Device Name: Diopsys™ NOVA VEP Vision Testing System

Indications For Use: The NOVA is an electrophysiological device that generates photic stimuli, and records, processes, and analyzes the resultant visual evoked potential (VEP) signals to provide information about the visual system structural and neural abnormalities.

Intended Use Population		Yes	No
Adults		X	
All pediatric patients age < 21 years old?			X
Neonate/Newborn	(Birth to 28 days)		X
Infant	(29 days – < 2 years old)	X	
Child	(2 years – < 12 years old)	X	
Adolescent	(12 years – < 18 years old)	X	
Transitional Adolescent A[1]	(18 years – < 21 years old)		X
Transitional Adolescent B[2]	(18 years – < 21 years old)	X	

[1] Compared to adults > 21 years old, this group receives special considerations (e.g., different device design or testing, different protocol procedures, etc.)

[2] No special considerations compared to adults > 21 years old

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 IF 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 K101763