K120104

510(k) Summary : Visionsearch1 System

MAY 21 2012

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Brand Name: Visionsearch1 System

Common Name: Multi focal visual evoked potential (mfVEP) device

Classification Name: (21CFR 882.1890) Evoked Response Photic Stimulator

Product Code: GWE

Predicate Device: RETIScan/RETIPort (K023525).

Date Prepared: 11 May 2012

Device Description: The Visionsearch1 System consists of specialist software and the supporting computer and peripherals.

The System displays multifocal visual patterns to evoke response in the retina which are transmitted to the visual cortex. The System then detects responses in the visual cortex using specific, validated third party EEG electrodes and biological amplifier. After analyzing the EEG, the System displays the electrical response from each segment of the retina. It also allows the user to compare the response time between eyes and compare an individual's measurements to those from a set of data that the user has compiled as reference.

Indications for Use: Electrophysiological Test Unit for quantifying the response to visual stimulation by measuring the Visual Evoked Potential.

Summary of Basis for Substantial Equivalence:

The Visionsearch1 is substantially equivalent to the RETIScan/RETIPort (K023525) for mfVEP measurement. Equivalence is based on both devices having the same intended use and technological characteristics as summarized in the following Comparison Table.

Feature	Predicate RETIscan (K023525)	Visionsearch1
Intended use	Generate photic signals and measure and display the electrical response signals generated by the retina and the visual nervous system.	Same as predicate
Intended users	Ophthalmologists and trained medical technicians and professionals	Same as predicate
Indications for use	Electrophysiological Test Unit for quantifying the retinal response and measuring parameters (VEP and ERG) related to retinal response.	Same as predicate for mfVEP functionality subset
Intended Population	Patients with ophthalmic conditions	Same as predicate
Intended Use environment	Hospitals, clinics and physician offices	Same as predicate
Physiological data collected	Electroretinogram and Visual Evoked Potential (VEP) waveforms	VEP waveforms
Principle of operation	Display multi-focal, light/dark patterns , read resultant waveforms, filter and correlate against stimulus patterns to produce response measurements. Key features: • Dartboard layout with 58 segments for mfVEP (1 innermost ring with 8 segments, 4 rings with 12 segments, 2 extra segments in nasal field. • Displayed on standard LCD monitor (60:000 to 1 contrast, 1.5 or greater LUX) at 24 degree field of view when patient is correctly positioned. • Uses m-sequence for temporal sequence generation. • Supports 60Hz stimulation rate. • Pattern reversal stimulation with 4*4 checkerboard in each segment. • Patient fixates on fixed icon or changing pattern (where they count the number of events and verbally inform the operator at	Same as predicate, except: • Only 56 segments are used (nasal field segments are not included). • More advanced patient fixation – a wireless device is used for patient feedback instead of verbal communication, and a 'multi response'/'multi button' fixation system is supported.

Feature	Predicate RETIscan (K023525)	Visionsearch1
	the end).	
Materials of construction	Enterprise grade PC with stimulus quality monitor and/or Ganzfeld-stimulator and/or Miniganzfeld-stimulator and integrated bio amplifier (2-8 channels).	Enterprise grade PC with stimulus quality monitor attached to 3rd party (independently certified) clinical bio amplifier (4 channels).
Functions offered by the software	Provision of stimulus patterns via computer monitor. Acquisition of evoked response through a bio amplifier. Display of waveforms captured by the amplifier during recording. Detection of noise and artifacts in the acquired response. Scaling and correlation of the response to the stimulus to produce amplitude and latency measurements. Resulting measurements are displayed in numerical and 2d/3d graphical formats. Comparisons between measurements and against user supplied reference sets are possible. Recordings can be exported and imported between systems. Measurements and graphs can be printed.	Same as predicate

Safety: The Visionsearch1 device complies with applicable standards for electrical and biological safety. It was developed in accordance with design control requirements of ISO13485:2003 and 21 CFR- 820.30. Software development was conducted in accordance with requirements of IEC 62304:2006 "Medical device software – Software lifecycle processes" and software validation was performed by an independent laboratory accredited by the Australian National Association of Testing Authorities (NATA) for testing and validation of medical device software. Electrical components in contact with the patient conform to IEC60601-1-2:2007. The isolation transformer powering all other electrical components complies with IEC 60601-1.

Effectiveness: Stimulus provided is essentially identical (in terms of luminance, chromaticity and size of the stimulated visual field) to that of the predicate. The effectiveness of data capture and analysis is validated

through development under IEC 62304 software life cycle controls and independent laboratory verification of software functionality.

Substantial equivalence conclusion

The new device, the Visionsearch1 System, is considered to be substantially equivalent to the predicate device based on:

- equivalent technological characteristics
- identical intended use
- identical indications for use
- identical users
- identical patient population

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

Brandwood Biomedical Pty. Ltd.
c/o Mr. Norbert Stuiber
TÜV SÜD America
1775 Old Hwy. 8 NW, Ste. 104
New Brighton, MN 55112-18914

MAY 21 2012

Re: K120104
Trade/Device Name: Visionsearch1 System
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: May 15, 2012
Received: May 17, 2012

Dear Mr. Stuiber:

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): K120104

Device Name: Visionsearch1 System

Indications For Use: Electrophysiological Test Unit for quantifying the response to visual stimulation by measuring the Visual Evoked Potential.

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)

Quynh Hoang

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

510(k) Number K120104