April 23, 2020

Cryptych Pty Ltd
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, Florida 33155-3708

Re: K200705
Trade/Device Name: Nurochek System
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked response photic stimulator
Regulatory Class: Class II
Product Code: GWE, OMC
Dated: April 21, 2020
Received: April 22, 2020

Dear Rafael Aguila:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K200705

Device Name

Nurochek System

Indications for Use *(Describe)*

The Nurochek System is intended for prescription use in healthcare facilities or clinical research environments for subjects ages 14 years and older. The Nurochek System is indicated for the generation of visual evoked potentials (VEPs) and to acquire, transmit, display and store electroencephalograms (EEGs) during the generation of VEPs. The Nurochek System only acquires and displays physiological signals: no claims are being made for use as a diagnostic criterion or for the analysis of the acquired signals with respect to the accuracy, precision and reliability.

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.

510(k) SUMMARY

for

Nurochek System

510(k) Owner: Cryptych Pty Ltd
Address: Level 15, Suite 1502
275 Alfred Street
North Sydney NSW 2060
Phone and fax numbers: +61 299 595 820

Name of contact person: Angela Roche

Trade Name: Nurochek System
Common Name: Visual Evoked Photic Stimulator
Classification name: Stimulator, Photic, Evoked Response

Regulation number: 882.1890

Product Code: GWE, OMC
Device Class: II
Manufacturer: Cryptych Pty Ltd
Submitter: Cryptych Pty Ltd

Preparation Date: March 05, 2020
Predicate Devices: SightSaver Visual Stimulator by Anschel Technology INC.(K113785)
X-Series System by Advanced Brain Monitoring (K131383)

DEVICE DESCRIPTION

The Nurochek System is indicated for the generation of visual evoked potentials (VEPs) and to acquire, transmit, display and store electroencephalograms (EEGs) during the generation of VEPs. The Nurochek System only acquires and displays physiological signals: no claims are being made for use as a diagnostic criterion or for the analysis of the acquired signals with respect to the accuracy, precision and reliability.

The Nurochek System combines hardware, firmware and software to generate and acquire physiological signals, specifically, VEPs. These VEPs are generated by a visual stimulus delivered through the Nurochek headset worn by the subject. This visual stimulus is a short-duration flash of white light. The Nurochek headset acquires the VEPs from the rear of the head and transmits the resulting EEG to the Nurochek software application to be displayed to the user and stored. These acquired signals are intended to be analyzed by a Physician.

The Nurochek System operates on the principles of generating VEPs via photic simulation and acquiring the VEPs via EEG. Photic stimulation is provided through short-duration flashes of white light from multiple LEDs located in the front of the headset to direct the stimulus into the subject's eyes. The VEPs are acquired by an EEG comprising of a total of 5 electrodes. Each electrode interfaces with hydrophilic foam cylinders saturated with saline solution to provide electrical contact to the subject's scalp. A Bluetooth receiver and

transmitter located within the Nurochek headset allows it to communicate with and be controlled by the Nurochek software application.

The Nurochek software application provides a graphical user interface which allows:

- Collection of the subject details and consent,
- Initiation of a study and tracking of patient information,
- Acquisition and transmission of signals wirelessly to and from the headset,
- Display of the contact quality of electrodes to the subject's scalp,
- Recording, processing and display of EEG signals received from the headset, and
- Manage previous EEG recordings of VEPs.

INTENDED USE

The Nurochek System is intended for prescription use in healthcare facilities or clinical research environments for subjects ages 14 years and older. The Nurochek System is indicated for the generation of visual evoked potentials (VEPs) and to acquire, transmit, display and store electroencephalograms (EEGs) during the generation of VEPs. The Nurochek System only acquires and displays physiological signals: no claims are being made for use as a diagnostic criterion or for the analysis of the acquired signals with respect to the accuracy, precision and reliability.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The Nurochek System uses the same fundamental technology as its predicates for the generation of visual-evoked potentials (VEPs) via photic stimulation, the capture of electroencephalograph (EEG) signals, wireless acquisition and software. The technologies used in the Nurochek System are used in the same manner as the predicate devices and do not raise new questions related to safety and effectiveness.

The Nurochek System is substantially equivalent to the legally marketed evoked-response photic stimulator and electroencephalograph (EEG) devices:

(1) Evoked-response photic stimulator technology:
Device name: SightSaver Visual Stimulator
510(k) number: K113785
510(k) submitter: Anschel Technology Inc.
Classification regulation: 882.1890
Product code: GWE

(2) Electroencephalograph technology:
Device name: X-Series System
510(k) number: K131383
Model number: X10 / X24
510(k) submitter: Advanced Brain Monitoring
Classification regulation: 882.1400
Product code: GWQ, OMC

The Nurochek headset is worn by a subject and combines hardware, firmware and software to generate and acquire physiological signals, specifically, visual-evoked potentials (VEPs). The Nurochek operates on the principles of generating VEPs via photic activation and acquiring the VEPs via EEG.

Photic activation is achieved through short-duration flashes of white light from multiple LEDs located in the front of the headset (LED visual stimulator goggle) to direct the stimulus into the subject's eyes. This is technologically equivalent to the SightSaver Visual Stimulator (K1113785).

The VEP is acquired by an EEG located on the rear part of the headset that contacts the subject's scalp (the sensor). The resulting EEG signal is transmitted via Bluetooth to the Nurochek software application to be displayed and stored. These acquired signals are intended to be analyzed by a Physician. This is technologically equivalent to X-Series System (K131383).

The Nurochek System uses software that is technologically equivalent to the X-Series System to control the headset and display the acquired physiological signals. Like the X-Series System, the Nurochek System only acquires and displays the physiological signals and makes no claims in relation to diagnoses.

Table 1 provides a summary of the comparison of the key features between the Nurochek System and its predicates: SightSaver Visual Stimulator and the X-Series System.

Table 1: Comparison table of Nurochek with predicates devices

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
Manufacturer	Cryptych Pty Ltd	Anschel Technology Inc	Advanced Brain Monitoring	N/A
K Number	**K_____**	**K113785**	**K131383**	**N/A**
Indications for Use	The Nurochek System is intended for prescription use in healthcare facilities or clinical research environments for subjects ages 14 years and older. The Nurochek System is indicated for the generation of visual evoked potentials (VEPs) and to acquire, transmit, display and store electroencephalograms (EEGs) during the generation of VEPs. The Nurochek System only acquires and displays physiological signals: no claims are being made for use as a diagnostic criterion or for the analysis of the acquired signals with respect to the accuracy, precision and reliability.	The SightSaver is an evoked response photic stimulator that is used to apply a visible light stimulus to a patient's eyes for use in evoked response measurements or for electroencephalogram (EEG) activation. The SightSaver Visual Stimulator is designed to be used in hospital and clinical settings by trained medical personnel and is for prescription use only.	The X-Series System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, transmit, display and store physiological signals from patients ages 6 and older. The X-Series system requires operation by a trained technician. The X-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer signals. The X-Series System only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.	**Equivalent** The predicate devices generate a visual stimulus and acquire, transmit, displays and store electroencephalograms (EEGs)
Patient population	Ages 14 and older	Children and adults	Ages 6 or older	**Equivalent** Patient population of the Nurochek System device is within the patient population of the predicates.
Users	Licensed healthcare professionals	Trained medical personnel	Trained Technician	**Equivalent** All devices require professional operators and are prescription only.
Anatomical sites for EEG readings	Scalp	N/A (does not measure patient)	Scalp and Chest	**Equivalent** Nurochek System's EEG sites are the same (the scalp) as the X-Series System. The chest site is not relevant as the Nurochek System does not utilize ECG technology.

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
Anatomical sites for visual stimulus	Periocular region of the patient's face	Periocular region of the patient's face	N/A (is not a visual stimulator)	**Equivalent** Both the Nurochek and SightSaver contact the periocular region of patient's face to deliver the visual stimulus.
Prescription use or OTC	Prescription use only	Prescription use only	Prescription use only	**Identical**
Environment of Use	Healthcare facility Clinical Research Environment	Hospital Clinical settings	Home Healthcare facility Clinical Research Environment	**Equivalent** Nurochek System and both predicates are used in a healthcare facility.
Cleaning	Cleaned and disinfected by rubbing with disinfectant wipes	N/A (the device is disposable)	Cleaned and disinfected by rubbing isopropyl alcohol	**Equivalent** The Nurochek headset is cleaned and disinfected to a higher standard. A higher standard is used due to the design of Nurochek's headset. The Nurochek headset contains an anterior visor while the X-series System does not. As tests were performed to demonstrated that cleaning methods are appropriate for ensuring the Nurochek headset is clean between uses they are considered equivalent.
Technical specifications				
User Interface	User control, visual indicators	N/A (does not contain any controls)	User control, visual indicators	**Equivalent** Nurochek System has same user interface features as X-Series System.
Wireless data transfer	Bluetooth	N/A (does not transfer data)	Bluetooth	**Equivalent** Nurochek uses the same technology as X-Series System.
Signals Acquired	Scalp EEG	N/A (does not acquire signals)	Scalp EEG 3-D actigraphy	**Equivalent** Nurochek System only utilizes scalp EEG technology and does not utilize 3-D actigraphy nor the optional channels of the X-Series

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
			Optional channels ECG/EEG/EOG/EMG	System. Therefore, the other signals are not relevant for the Nurochek System.
Power Supply	3.7V, 800 mAH Li-Ion battery	Externally powered by trigger device.	2 to 4 240mAH 3.7V, 240mAH Li-Ion batteries	**No Significant Differences** Both Nurochek System and X-series System use rechargeable 3.7V lithium-ion batteries. The difference in charge capacity and number of batteries, which only dictates the length of use. The SightSaver is to be connected to a separate control device which supplies the power.
Operating time	After full charge, unit is capable of at least 30 complete tests (30 minutes)	N/A (controlled by external trigger)	Monitoring days after charge hours of use: 0-4 days: 16 to 17 hours 5-10 days: 14 to 15 hours.	**No significant differences** The Nurochek System is indicated for short-term use i.e. 2 sets of 30 second tests completed consecutively. The X-Series System is indicated for long-term monitoring over a large period of time.
Battery Charging	Via USB cable from a wall charger	N/A (does not contain battery)	Via JED Connector connected to the USB port or USB wall charger	**Equivalent** The charging mechanisms between the Nurochek System and X-Series System are the same, differing only in the connector style which does not affect safety of Nurochek System.
Typical Charging Time	Typical: 0.5- 3 hours	N/A (does not contain battery)	Typical: 0.5-5 hours.	**No significant difference** The charging time for a full charge for the Nurochek device is less than the X-Series System, allowing it to be used more frequently.
Photic Stimulation Technology				
Mode of Operation	Photic stimulator positioned on the periocular region of the patient's face to expose the eyes to LED light in order to generate a physiological response.	Photic stimulator positioned on the periocular region of the patient's face to expose the eyes to LED light in order to generate a physiological response.	N/A (does not contain photic stimulation technology)	**Equivalent** The Nurochek uses the same visual stimulator LED technology as the

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
				SightSaver to generate a physiological response.
Light source	LED	LED	N/A (does not contain photic stimulation technology)	**Equivalent** The Nurochek System uses the same technology of light (Light-emitting diodes - LED) as the SightSaver device.
Flash Rate	15Hz fixed	Typically 0.5-1.0Hz, up to 100Hz	N/A (does not contain photic stimulation technology)	**Equivalent** The SightSaver's flash rate depends on the external trigger. There is no limiting mechanism on the SightSaver itself. For example, when used with the Nicolet Viking EDX (K112052), the flash rate can be set to 0.1-100Hz. Flash rate of the Nurochek headset light stimulus is fixed to 15Hz, which is within the capabilities of the SightSaver.
EEG Technology				
Electrodes Material	Hydrophilic polyurethane foam on gold plated copper	N/A (does not contain EEG technology)	Ag/AgCl	**No significant difference** Both electrodes achieve the same function. Material difference has been tested and does not affect safety and efficacy of Nurochek System.
Definition	3 EEG scalp channels	N/A (does not contain EEG technology)	Up to 20 EEG scalp channels	**Equivalent** The Nurochek System uses a subset of the channels of the predicate device. The additional number of channels on the predicate device will go unused when used for the detection of VEPs: this is because only 3 electrode sites (O1, O2 and Oz) correspond to the visual cortex.
Signal processing techniques	Sampling rate: 250 s/s	N/A (does not contain EEG technology)	Sampling rate: 256 s/s 0.1 Hz High Pass, hardware	**Equivalent**

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
	Digital decimation filters		100 Hz Low Pass, hardware	A sampling rate difference only dictates the maximum frequency that can be interpreted. Different filtering systems are used but both achieve the same goal not affecting the safety and effectiveness of Nurochek System.
Accuracy, variance and error of measurements, in comparison to standard techniques of measuring identical physiologic variables.	Sampling rate: 250 Hz Dynamic range: +/- 187,500 µV Resolution: 0.02µV Peak to peak noise: 1.97µV (typical) 110 dB Common rejection ratio Input impedance: 1GOhm	N/A (does not contain EEG technology)	Sampling rate: 256 Hz Dynamic range: +/- 1000µV Resolution: 0.03µV Peak to peak noise: 3.7µV (typical) 110 dB Common Mode Rejection Ratio (typically) Input impedance: 100GOhm	**Equivalen**t Aa above, a sampling rate difference only dictates the maximum frequency that can be interpreted. The dynamic range on the Nurochek System is larger (and therefore superior) than the X-Series System. The dynamic range of the Nurochek exceeds that of the X-Series system. A higher dynamic range means a wider range of voltages may be interpreted without saturation. Nurochek System exceeds the resolution performance of the X-Series System. A lower resolution number means the Nurochek System can resolve smaller differences in the signal, making it more accurate The Nurochek System has a lower peak-to-peak noise of the X-Series System. A lower peak-to-peak noise level means that the noise will have less of an effect on the system. Both devices have the same common mode rejection ratio.

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
				International Organisation of Societies for Electrophysiological Technology (OSET) recommends at least 10 MOhm, which both devices exceed substantially.
Impedance Check	Yes	N/A (does not contain EEG technology)	Yes	**Equivalent** The Nurochek System and the X-Series System both have an impedance check.
Safety and Performance				
Electrical	IEC 60601-1:2013 IEC 60601-2-40	Unknown	IEC 60601-2-26:2002 IEC 60601-1-11: 2010 IEC 60601-1:1998+A1: 1991+A2: 1995	**Equivalent** The Nurochek System uses more up-to-date standards. IEC 60601-2-26 is not used as IEC 60601-2-40 is more suitable for devices with evoked response equipment. IEC 60601-1-11:2010 is not used as it applies to home use devices only.
Electromagnetic Compatibility	IEC 60601-1-2:2014	Unknown	IEC 60601-1-2: 2007	**Equivalent** The Nurochek System uses more up-to-date standards.
Light Safety	ISO 15004:2 ANSI Z80.36	ISO 15004:2	N/A (no visual stimulus)	**Equivalent** The Nurochek System uses the same standard as the predicate, as well as an additional FDA recognized standard for light safety.
Software	FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices Document (May 11, 2005) FDA Guidance for Content of Premarket Submission for Management of Cybersecurity of Medical Devices	N/A (does not contain software)	FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices Document (May 11, 2005)	**Equivalent** The Nurochek System uses the same FDA guidance as the predicate, as well as an additional FDA guidance for cybersecurity.

Device Name	Subject device: Nurochek System	Primary Predicate SightSaver Visual Stimulator	Predicate X-Series System	Discussion
Usability and Human Factors	IEC 62366 FDA Guidance on Applying Human Factors and Usability Engineering to Medical devices	Unknown	Unknown	N/A
Cleaning	AAMI TIR 12:2010 AAMI TIR 30:2011 Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. 2015	N/A	AAMI TIR 12-94 AAMI TIR 30: 2003	**Equivalent** Same methods; more up-to-date standards for reprocessing method validation. An additional FDA guidance was used.
Biocompatibility	ISO 10993-5 – Cytotoxicity ISO 10993-10 - Sensitization ISO 10993-10 - Irritation	Unknown	ISO 10993-5 – Cytotoxicity ISO 10993-10 - Sensitization ISO 10993-10 - Irritation	**Equivalent** The Nurochek System uses the same standards for biocompatibility as the X-Series System.

NON-CLINICAL PERFORMANCE DATA

The Nurochek was developed and manufactured with risk management and safety testing, including electrical safety, biological safety, performance and software testing. This testing has provided assurance of safety and effectiveness within the scope of its intended use.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

Electrical safety and EMC testing were conducted on the Nurochek consisting of the headset, firmware and software.

Electrical safety and performance testing were conducted as per IEC 60601-1 (including collateral IEC 60601-1-2 for EMC testing and particular standard IEC 60601-2-40). Compliance to IEC 60601-2-40:2002 – 'Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment' was also conducted.

All test results demonstrated compliance of the Nurochek to standards for electro-medical equipment.

LIGHT SAFETY

Light safety testing was conducted as per ISO 15004-2:2007 and ANSI Z80.36-2016. Testing to both standards classified the Nurochek Headset as a Group1 Instrument. Both standards define a Group 1 instrument as: ophthalmic instruments for which no potential light hazard exists. Therefore, use of the Nurochek system as per the IFU will not lead to patient or user harm due to optical radiation.

BIOCOMPATIBILITY

Biocompatibility was assessed following FDA Guidance "Use of International Standard ISO10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Per Table 1 of the guidance, the Nurochek headset is a surface device with limited contact (Category A, less than 24 hours contact) and thus cytotoxicity, sensitization, and irritation reactivity tests were selected. Test methods were performed as per the relevant ISO 10993 standards series for Biological Evaluation of Medical Devices. These standards include cytotoxicity (ISO 10993-5), skin irritation and sensitization (ISO 10993-10). All contacting parts were evaluated, including the foam cylinders and strap components. Results of biocompatibility testing demonstrate that materials of the Nurochek System in contact with the patient are biocompatible.

CLEANING

The Nurochek headset cleaning and disinfection procedures have been validated in compliance with the FDA Guidance Document "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling". Testing was performed in accordance with recommended evaluations according to AAMI TIR30 and AAMI TIR12. All tests passed and demonstrated that the cleaning methods are appropriate for ensuring the Nurochek System is clean between uses.

MECHANICAL TESTING

Cyclic testing was performed to test the durability of the mechanical components of the Nurochek headset. The testing was to ensure that the device will meet its required use lifetime. This cyclic testing includes simulating the fitting, lifting and removal of the Nurochek headset on a patient's head.

Drop, impact and push tests as per IEC 60601-1 Ed. 3.1. were also performed to ensure the Nurochek headset is sufficiently resilient against foreseeable misuse.

All test passed and demonstrated compliance of the Nurochek System to IEC 60601-1 criteria.

FIRMWARE AND SOFTWARE

The firmware in the Nurochek headset and the Nurochek software have been thoroughly tested through verification and validation testing, including software validation as recommended by FDA's "Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", and according to IEC 62304.

The results of the verification and validation activities performed demonstrate the software meets requirements for safety, function and intended use.

CLINICAL STUDIES

A clinical study was performed to evaluate the functionality of the Nurochek System – headset, firmware and software. The study used the clinical EEG Compumedics Grael EEG as a reference device and benchmark. Compumedics Grael EEG is cleared by FDA under K093223, however, is not a predicate of this 510(k) submission. Data from 20 participants were compared to the Compumedics Grael EEG in its performance to detect steady-state visual-evoked potentials (SSVEPs). Participants were evaluated on the clinical EEG and the investigational device with a common visual stimulus shared between them.

All tests were performed successfully with no adverse events. The study concluded that both systems functioned identically in their ability to detect SSVEPs.

CONCLUSION

Cryptych considers the Nurochek System to be as safe and effective as the predicate devices and, therefore, substantially equivalent. The Nurochek System does not introduce any new questions concerning safety or efficacy. As demonstrated by the results from the non-clinical and clinical tests performed, the Nurochek System is safe and effective and meets the pre-defined design and performance acceptance criteria. The Nurochek System and its predicates, the SightSaver Visual Stimulator and X-Series System, have the same intended use and similar indications, technological characteristics and principles of operation. Therefore, the Nurochek System is substantially equivalent to the SightSaver Visual Stimulator and the X-Series System.