December 27, 2023

Headsafe MFG Pty Ltd.
% Erin Gontang, Ph.D.
Senior Consultant
RQM+
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K231914
Trade/Device Name: Nurochek-II System
Regulation Number: 21 CFR 882.1450
Regulation Name: Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid
Regulatory Class: Class II
Product Code: PIW, OMC
Dated: November 24, 2023
Received: November 27, 2023

Dear Erin Gontang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D.
Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231914

Device Name
Nurochek-II System

Indications for Use *(Describe)*
The Nurochek-II System is intended for prescription use in healthcare facilities for subjects aged between 16 and 46 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment.

The Nurochek-II 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. Additionally, the system is indicated to analyze captured EEG signals to provide an aid in the diagnosis of mild traumatic brain injury (mTBI) in subjects aged between 16 and 46 years old who have sustained a potential head injury in the past 72 hours (3 days).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K231914

DATE PREPARED
December 26, 2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Nurochek-II System
Common Name:	Brain injury adjunctive interpretive electroencephalograph assessment aid
Regulation Number:	21 CFR 882.1450
Class:	II
Product Code:	PIW, OMC
Premarket Review:	Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)
Review Panel:	Neurology

PREDICATE DEVICE IDENTIFICATION
The Nurochek-II System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K190815	BrainScope TBI / BrainScope Company, Inc.	✓
DEN170091/K191183	EyeBOX / Oculogica Inc.	Reference
K200705	Nurochek System / Headsafe MFG Pty Ltd.	Reference

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The Nurochek-II System is a portable system designed to generate visual evoked potentials (VEPs) in patients and acquire, transmit, display, and store the resulting electroencephalogram (EEG). It is intended for prescription use in healthcare facilities for subjects aged between 16 and 46 years, to aid in the diagnosis of mild traumatic brain injury (mTBI). The primary components of the Nurochek-II System are the wearable headset, the Nurochek-II software application, and the Nurochek-II server.

INDICATIONS FOR USE

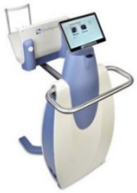
The Nurochek-II System is intended for prescription use in healthcare facilities for subjects aged between 16 and 46 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment.

The Nurochek-II 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. Additionally, the system is indicated to analyze captured EEG signals to provide an aid in the diagnosis of mild traumatic brain injury (mTBI) in subjects aged between 16 and 46 years old who have sustained a potential head injury in the past 72 hours (3 days).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Headsafe believes that the Nurochek-II System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design to the device cleared in K190815. It is also identical in physical design and materials to the reference device, the Nurochek System cleared in K200705. Both the subject and predicate devices are worn on the head to record and analyze electroencephalograms (EEGs). They are both intended to aid in the diagnosis of mild traumatic brain injury (mTBI) through the analysis of these recorded EEGs. See below for a table comparing the device's technological characteristics.

	Subject Device	***Predicate Device***	***Reference Device***	***Reference Device***
	Headsafe Nurochek-II System K231914	BrainScope Company, Inc. BrainScope TBI K190815	Oculogica Inc. EyeBOX DEN170091/K191183	Headsafe Nurochek System K200705
Image				
Indications for Use	The Nurochek-II System is intended for prescription use in healthcare facilities for subjects aged between 16 and 46 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment. The Nurochek-II 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. Additionally, the system is indicated to analyze captured EEG signals to provide an aid in the diagnosis of mild traumatic brain injury (mTBI) in subjects aged between 16 and 46 years old who have sustained a potential head injury in the past 72 hours (3 days).	BrainScope TBI is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury, and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion/mild traumatic brain injury (mTBI)).	The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion, <u>also known as mild traumatic brain injury (mTBI)*,</u> within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion. *underlined text indicates IFU update in K191183.	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.
Product Codes / Regulation Number	PIW, OMC 21 CFR 882.1450	PIW, PKQ, OLU 21 CFR 882.1450	QEA 21 CFR 882.1455	GWE, OMC 21 CFR 882.1890
Regulation Description	Brain injury adjunctive interpretive electroencephalograph assessment aid	Brain injury adjunctive interpretive electroencephalograph assessment aid	Brain injury adjunctive interpretive oculomotor assessment aid	Evoked response photic stimulator
Components	Software in a mobile application, reusable headset (LED lights in front, EEG electrodes in back)	Software on handheld device, disposable electrode headset	A PC with integrated touchscreen interface, eye tracking camera, LCD stimulus screen, head-stabilizing rests for chin and forehead, and data processing algorithm	Software in a mobile application, reusable headset (LED lights in front, EEG electrodes in back)

	Subject Device	*Predicate Device*	*Reference Device*	*Reference Device*
	Headsafe Nurochek-II System K231914	BrainScope Company, Inc. BrainScope TBI K190815	Oculogica Inc. EyeBOX DEN170091/K191183	Headsafe Nurochek System K200705
Power source	Rechargeable 3.7V lithium-ion battery	Rechargeable	Mains power input	Rechargeable 3.7V lithium-ion battery
Inputs	Patient identifying information	Patient identifying information	Patient identifying information	Patient identifying information
Electrode Placement	Occipital lobe	Frontal lobe	None	Occipital lobe
Outputs	• EEG • Quality of electrode contact with patient • Assessment of mTBI likelihood	• Concussion index • Structural injury classification • Brain function index	• Concussion score	• EEG • Quality of electrode contact with patient • Signal-to-noise ratio
Data Analysis & Storage	Records and stores EEGs Compares results to normative EEG data.	Records and stores EEGs Compares results to normative EEG data.	Records gaze positions 500 times per second. Processed data are analyzed automatically to produce a EyeBOX score/clinical report.	Records and stores EEGs Compares results to normative EEG data.
Patient interface	Worn on patient's head for 2 minutes.	Worn on patient's head for 10-30 minutes.	Patient's rests chin and forehead for ~4 minutes.	Worn on patient's head for 2 minutes.
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Reuse	Headset is reusable (Foam cylinders for electrodes are single use only)	Electrodes are disposable Handheld device is reusable	Reusable	Headset is reusable (Foam cylinders for electrodes are single use only)
Sensitivity	0.8605 95% confidence intervals (0.7207, 0.9470)	0.8599 95% confidence intervals (0.8050, 0.9041)	0.8040 95% confidence intervals (0.6610, 0.9190)	N/A
Specificity	0.6716 95% confidence limits of (0.5460, 0.7815)	0.7078 95% confidence limits of (0.6588, 0.7535)	0.6610 95% confidence limits of (0.5970, 0.7210)	N/A
Patient Population	Patients 16-46 years who have sustained a potential head injury in the past 72 hours (3 days)	Patients between the ages of 13–25 years who present with a GCS score of 15 following a head injury within the past 72 hours (3 days)	Patients between the ages of 5 to 67 years old who have sustained a head injury within the past week	Patients 14 years and older

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Nurochek-II System. The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility:

The subject device was evaluated for cytotoxicity, sensitization, and irritation in compliance to ISO 10993-5:2009 and ISO 10993-10:2010.

Software Verification:

The software development and testing were executed with consideration to IEC 62304.

Electromagnetic Compatibility and Electrical Safety:
The subject device was tested in compliance to IEC 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-2-40:2016.

SUMMARY OF CLINICAL TESTING
The primary objective of the clinical investigation was to evaluate the performance of the Nurochek-II System against clinical diagnosis by a licensed healthcare professional in the accurate detection of mild traumatic brain injury (mTBI). The study demonstrated that the device can differentiate between subjects with and without mTBI.

The Headsafe classification algorithm used in this device was generated with 372 individual steady-state visual-evoked potential (SSVEP) readings, in which there was an 11% prevalence of mTBI. The SSVEP readings from the study subjects (age range 14-55 years) were used to generate the database, to which the device compares new results. The clinical research protocol required readings to be collected within 72 hours of the suspected head injury, in addition to a clinical evaluation by a licensed physician. Each highly trained physician used their education and experience to deliver their mTBI determination. At the core of each assessment was a neurological examination, a concussion-related signs and symptom evaluation, and a review of all relevant information provided by the study subject in relation to their injury. A separate validation data set consisting of 110 individual SSVEP readings, in which there was a 39.1% prevalence of mTBI in the population (age range 16-46 years), resulted in a sensitivity of 86% (72.07-94.70, 95% confidence interval) and a specificity of 67% (54.60-78.15, 95% confidence interval). The resulting positive predictive value (PPV) and negative predictive value (NPV) were 62.7% and 88.2%, respectively. The table below tabulates the performance of the Nurochek-II System from this 110-individual study and compares it to the predicate and reference device based on publicly available information from their 510(k) and De Novo decision summaries.

Device [FDA Reference #]	Nurochek-II System [K231914]	BrainScope TBI [K190815]	EyeBOX [DEN170091/K191183]
	Subject Device	Predicate Device	Reference Device
Sensitivity % [95% CI]	86.05 [72.07-94.70]	85.99 [80.50-90.41]	80.40 [66.10-91.90]
Specificity [95% CI]	67.16 [54.60-78.15]	70.78 [65.88-75.35]	66.10 [59.70-72.10]
#Patients clinically diagnosed as Concussed	43	207	46
#Patients clinically diagnosed as not concussed	67	373	236
Prevalence of mTBI in Validation Study	39.1	35.69	16.31
Positive Predictive Value (PPV) % [95% CI]	62.7 [53.92-70.75]	62.0	31.6 [26.89-36.73]
Negative Predictive Value (NPV) % [95% CI]	88.2 [77.79-94.13]	90.1	94.5 [90.56-96.91]

CONCLUSION

Based on the testing performed, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Nurochek-II System are assessed to be substantially equivalent to the predicate devices.