



March 27, 2025

Headsafe MFG Pty Ltd.  
% Erin Gontang, Ph.D.  
Senior Consultant  
RQM+  
2790 Mosside Blvd., Suite 800  
Monroeville, Pennsylvania 15146

Re: K243426

Trade/Device Name: Nurochek-Pro 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: February 25, 2025

Received: February 25, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Patrick  
Antkowiak -S

For 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

## Indications for Use

Submission Number (if known)

K243426

Device Name

Nurochek-Pro System

Indications for Use (Describe)

The Nurochek-Pro System is intended for prescription use in healthcare facilities for subjects aged between 12 and 44 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment.

The Nurochek-Pro System is indicated for the generation of visual evoked potentials (VEP) and to acquire, transmit, display, and store electroencephalograms (EEG) 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 12 and 44 years old who have sustained a potential head injury in the past 120 hours (5 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**  
K243426

**DATE PREPARED**

March 27, 2025

**MANUFACTURER AND 510(k) OWNER**

Headsafe MFG Pty Ltd.  
61 Marlborough Street, Suite 76  
Surry Hills NSW 2010  
Australia  
Telephone: +61 418 25 3333  
Official Contact: Adrian Cohen, MD, CEO

**REPRESENTATIVE/CONSULTANT**

Erin A. Gontang, PhD  
RQM+  
Telephone: +1 (412) 899-7422  
Email: egontang@rqmplus.com

**DEVICE INFORMATION**

Proprietary Name/Trade Name: Nurochek-Pro 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-Pro System is substantially equivalent to the following predicate:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K231914	Nurochek-II System / Headsafe MFG Pty Ltd.	✓

The predicate device has not been subject to a design related recall.

### **DEVICE DESCRIPTION**

The Nurochek-Pro 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, by healthcare professionals, on subjects aged between 12 and 44 years old, to aid in the diagnosis of mild traumatic brain injury (mTBI). The primary components of the Nurochek-Pro System are the wearable headset, the Nurochek-Pro Software Application, and the Nurochek-Pro Server.

### **INDICATIONS FOR USE**

The Nurochek-Pro System is intended for prescription use in healthcare facilities for subjects aged between 12 and 44 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment.

The Nurochek-Pro System is indicated for the generation of visual evoked potentials (VEP) and to acquire, transmit, display, and store electroencephalograms (EEG) 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 12 and 44 years old who have sustained a potential head injury in the past 120 hours (5 days).

### **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

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

The subject device has a nearly identical design to the Nurochek-II System cleared in K231914. Both the subject and predicate device 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.

	<b><i>Subject Device</i></b>	<b><i>Predicate Device</i></b>
	Headsafe Nurochek-Pro System K243426	Headsafe Nurochek-II System K231914
<b>Indications for Use</b>	<p>The Nurochek-Pro System is intended for prescription use in healthcare facilities for subjects aged between 12 and 44 years old, for the aid in diagnosis of mild traumatic brain injury (mTBI) in conjunction with a standard neurological assessment.</p> <p>The Nurochek-Pro 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 mTBI in subjects aged between 12 and 44 years old who have sustained a potential head injury in the past 120 hours (5 days).</p>	<p>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.</p> <p>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).</p>
<b>Product Codes / Regulation Number</b>	PIW / 21 CFR 882.1450 OMC / 21 CFR 882.1400	PIW / 21 CFR 882.1450 OMC / 21 CFR 882.1400
<b>Regulation Description</b>	Brain injury adjunctive interpretive electroencephalograph assessment aid	Brain injury adjunctive interpretive electroencephalograph assessment aid
<b>Components</b>	Software in a Windows desktop application, reusable headset (LED lights in front, EEG electrodes in back)	Software in a mobile application, reusable headset (LED lights in front, EEG electrodes in back)
<b>Power source</b>	Mains power supply (via a USB-A connection to computer)	Rechargeable 3.7V lithium-ion battery
<b>Inputs</b>	Patient identifying information	Patient identifying information
<b>Electrode Placement</b>	Occipital lobe	Occipital lobe
<b>Electrode Channels</b>	Recording (3) Reference (1) Ground (1)	Recording (3) Reference (1) Ground (1)
<b>Signal Amplification</b>	Programmable gain amplifier (PGA) setting (same as predicate)	Programmable gain amplifier (PGA) setting (same as subject)

	<i>Subject Device</i>	<i>Predicate Device</i>
	Headsafe Nurochek-Pro System K243426	Headsafe Nurochek-II System K231914
<b>Connection Hardware to Software</b>	Wired connection (USB-A)	Wireless Connection (Bluetooth)
<b>Software Interface</b>	Computer	Handheld device
<b>Outputs</b>	<ul style="list-style-type: none"> <li>• EEG</li> <li>• Quality of electrode contact with patient</li> <li>• Assessment of mTBI likelihood</li> </ul>	<ul style="list-style-type: none"> <li>• EEG</li> <li>• Quality of electrode contact with patient</li> <li>• Assessment of mTBI likelihood</li> </ul>
<b>Data Analysis &amp; Cloud Storage</b>	Records and stores EEGs Compares results to normative EEG data	Records and stores EEGs Compares results to normative EEG data
<b>Patient interface</b>	Worn on patient's head for 2 minutes	Worn on patient's head for 2 minutes
<b>Sterilization</b>	Non-sterile	Non-sterile
<b>Reuse</b>	Headset is reusable (Silver-tipped rubber electrodes are reusable)	Headset is reusable (Foam cylinders for electrodes are single use only)
<b>Sensitivity</b>	0.8551 95% confidence limits of (0.7496, 0.9283)	0.8605 95% confidence intervals (0.7207, 0.9470)
<b>Specificity</b>	0.6705 95% confidence limits of (0.5621, 0.7670)	0.6716 95% confidence limits of (0.5460, 0.7815)
<b>Patient Population</b>	Subjects aged between 12 and 44 years old who have sustained a potential head injury in the past 120 hours (5 days)	Subjects aged between 16 and 46 years old who have sustained a potential head injury in the past 72 hours (3 days)
<b>Use Environment</b>	Healthcare facilities	Healthcare facilities
<b>Device Operator</b>	Healthcare professional	Healthcare professional

**SUMMARY OF NON-CLINICAL TESTING**

No FDA performance standards have been established for the Nurochek-Pro 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 ISO10993-5:2009 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-Pro 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 272 individual steady-state visual-evoked potential (SSVEP) readings, in which there was a 24.6% prevalence of mTBI. The SSVEP readings from the study subjects (age range 12-49 years) were used to generate the database, to which the device compares new results. The clinical research protocol required readings to be collected within 120 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 dataset consisting of 157 individual SSVEP readings, in which there was a 43.9% prevalence of mTBI in the population, resulted in a sensitivity of 85.51% (74.96-92.83, 95% confidence interval) and a specificity of 67.05% (56.21-76.70, 95% confidence interval). The resulting Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were 67.0% and 85.5%, respectively.

	<i>Subject Device</i>	<i>Predicate Device</i>
	Headsafe Nurochek-Pro System K243426	Headsafe Nurochek-II System K231914
<b>Sensitivity % [95% CI]</b>	85.51 [74.96-92.83]	86.05 [72.07-94.70]
<b>Specificity % [95% CI]</b>	67.05 [56.21-76.70]	67.16 [54.60-78.15]
<b>#Patients Clinically Diagnosed as Concussed</b>	69	43
<b>#Patients Clinically Diagnosed as Not Concussed</b>	88	67
<b>Prevalence of mTBI in Validation Study %</b>	43.9	39.1
<b>Positive Predictive Value (PPV) %</b>	67.0	62.7
<b>Negative Predictive Value (NPV) %</b>	85.5	88.2

**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-Pro System are assessed to be substantially equivalent to the predicate device.