June 29, 2023

Neurobit Technologies Co., Ltd.
% Tyra Chiu
Regulatory Consultant
Intellrac Consulting Ltd.
1 F., No. 28, Ln. 18, Shude 1st. St., Taiping Dist.
Taichung City, 411
Taiwan

Re: K223047
Trade/Device Name: NeuroSwift Pro
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: May 1, 2023
Received: May 30, 2023

Dear Tyra Chiu:

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223047

Device Name
NeuroSwift Pro

Indications for Use *(Describe)*
NeuroSwift Pro is intended for Viewing and recording eye movements in support of identifying vestibular disorders.The system is to be used by trained healthcare personnel in an appropriate healthcare setting. This system provides no diagnosis and does not provide diagnostic recommendations. The target population is 12+ years of age.

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.

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510(k) Summary

Date: June 28, 2023

Manufacturer: Neurobit Technologies Co., Ltd.
2F, No.320 Sec. 4, Zhongxiao E. Rd. Taipei City, 106, Taiwan.
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Phone: +886-2-27710618
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Device: Trade Name: NeuroSwift Pro
Common Name: Nystagmograph
Classification Names: Nystagmograph
Device Class II
Classification Panel: Neurology
Product Code: GWN
Regelation Number 882.1460

Device Description And Technology Characteristics

The NeuroSwift Pro is intended for viewing and recording eye movements in support of identifying vestibular disorders. The system is to be used by trained healthcare personnel in an appropriate healthcare setting. This system provides no diagnosis and does not provide diagnostic recommendations. NeuroSwift Pro, model NS01-2 contains goggles and software. The NeuroSwift Pro is a combination of hardware and software, designed to provide information for clinicians as a supplement in clinical decision-making by eye movements. The NeuroSwift Pro goggle is a see-through binocular video goggle with a pair of light reflectors and 3 metered, nylon braided USB cable connecting to the computer interface. Accompanying components include a stable and sturdy head strap, face cushion, and a lightweight eye cover. The hardware provides high-definition video recording capability. The NeuroSwift Pro software is a computer interface designed to record eye movement videos and simultaneously display the visual target(s) on the

computer screen. The software provides vestibular test modes and calibration functions. Initially, the software instructs the users to follow calibration functions. Then, the examiner can observe spontaneous nystagmus using the eye cover. The examiner can perform oculomotor tests with the goggles, while the patient follows visual targets on the screen. During gaze tests, the patient will fixate on stationary white spots that are positioned at center, right, left, up and down. In saccade tests the patient is asked to stare at the target moving in horizontal, vertical, or mixed pattern. In pursuit tests the patient's ability to track a target that moves in a sinusoidal or triangular pattern across the screen. The optokinetic function provides a large moving checkerboard pattern on the screen. Patients can change in various body positions as directed by the clinician. The software measures the eye movement via slow phase velocity and measures the eye position shift and trace. The recorded video and test protocols are processed in the NeuroSwift Pro software. The NeuroSwift Pro generates the traces of eye movements, eye velocities, and analytical data, which allows the clinician to determine the response of the patient according to the test functions.

The device contains the following vestibular test protocols:

- Calibration
- Spontaneous nystagmus test
- Gaze test
- Saccade test
- Pursuit test
- Optokinetic test
- Positional test

Intended Use NeuroSwift Pro is intended for viewing and recording eye movements in support of identifying vestibular disorders. The system is to be used by trained healthcare personnel in an appropriate healthcare setting. This system provides no diagnosis and does not provide diagnostic recommendations. The target population is 12+ years of age.

Predicate Device(s):

Predicate Device	Manufacturer	510(K) Number
VisualEyes 505/515/525	INTERACOUSTICS A/S	K200534

Substantial Equivalence

The subject device has same intended use, technology, operation principle and technical characteristics with the predicate device(s). Design Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the intended use of the device or raise any unsolved issues. There are no significant differences between subject device and the predicate device(s) that would adversely affect the use of the product. We conclude that subject device is substantially equivalent to predicate devices.

	Subject Device NeuroSwift Pro	**Predicate Device** VisualEyes 505/515/ 525	**Equivalence Discussion**
510(k) number	K223047	K200534	--
Product code	GWN	GWN	Same
Classification	Class II	Class II	Same
Indications for use	NeuroSwift Pro is intended for viewing and recording eye movements in support of identifying vestibular disorders. The system is to be used by trained healthcare personnel in an appropriate healthcare setting. This system provides no diagnosis and does not provide diagnostic recommendations. The target population is 12+ years of age.	The VisualEyes system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by use of a goggle mounted with cameras. These images are measured, recorded, displayed and stored in the software. This information then can be used by a trained medical	Similar. The age limitation is different. The NeuroSwift Pro goggle is not designed for children under 12 as it may not fit smaller faces adequately. We assess it as having similar indications, considering it as a practical limitation.

		professional to assist in diagnosing vestibular disorders. The target population for VisualEyes system is 5 years of age and above.	
Technology	Eye-tracking software and manufacturer-provided hardware.	Eye-tracking software to be used with various goggle / cameras, rotary chairs, irrigators and other accessories	Same. Both use tracking software and goggles to achieve their intended use.
Operation Principle	Infrared video cameras mounted inside goggle display the patient's eye movements on a connected computer. The goggles are light-weight and equipped with adjustable head band. The eye cover part is designed with magnet attachment to be easily attach/ detach to the goggle. The cameras are connected to the computer via USB cable. The software on the connected computer is performed to support the recording, viewing, monitoring and analyzing of eye position and movement.	VisualEyes 505/515/525 is a software program that analyzes eye movements recorded from a camera mounted to a video goggle. The VisualEyes is a software system is intended to incorporate various goggle/cameras, rotary chairs, irrigators and other accessories.	Same. Both use wearable cameras and software to display and record the patient's eye movement.
Weight	400 g (face cushion, eye cover, goggle and cable)	Side mounted camera goggles 385 g (occluded view)	Similar. The non-clinical and clinical performance testing confirm that both devices meet

<table>
<tr><td></td><td></td><td></td><td>the required safety and effectiveness standards, fulfilling the intended use.</td></tr>
<tr><td>Materials</td><td>Polyamide, glass</td><td>Unknown</td><td>Different.
The Biocompatibility evaluation confirms that the subject device does not raise new questions of biocompatibility.</td></tr>
<tr><td>Infrared (IR) Source</td><td>(2) IR LEDs @ 940 nm wavelength</td><td>Dual IR LED infrared illumination: 940 nm</td><td>Same</td></tr>
<tr><td>Infrared (IR) Control</td><td>On when goggles are plugged in and system is on.</td><td>On when goggles are plugged in and system is on.</td><td>Same</td></tr>
<tr><td>Energy Source</td><td>External via USB powered by computer</td><td>External via USB powered by computer</td><td>Same</td></tr>
<tr><td>Test protocols</td><td colspan="2"><table>
<tr><th>Test Battery</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>Calibration</td><td>●</td><td>●</td></tr>
<tr><td>Spontaneous nystagmus</td><td>●</td><td>●</td></tr>
<tr><td>Gaze</td><td>●</td><td>●</td></tr>
<tr><td>Saccade</td><td>●</td><td>●</td></tr>
<tr><td>Pursuit</td><td>●</td><td>●</td></tr>
<tr><td>Optokinetic</td><td>●</td><td>●</td></tr>
<tr><td>Positional</td><td>●</td><td>●</td></tr>
<tr><td>Dix-Hallpike</td><td></td><td>●</td></tr>
<tr><td>Caloric</td><td></td><td>●</td></tr>
<tr><td>Saccadometry</td><td></td><td>●</td></tr>
<tr><td>Sinusoidal Harmonic Acceleration</td><td></td><td>●</td></tr>
<tr><td>Step Velocity</td><td></td><td>●</td></tr>
<tr><td>VOR Suppression</td><td></td><td>●</td></tr>
<tr><td>Visual VOR</td><td></td><td>●</td></tr>
<tr><td>Subjective Visual Vertical (SVV) – Static/Dynamic</td><td></td><td>●</td></tr>
</table></td><td>Different.
The test protocol of the subject device is a subset of the test protocol of the predicate device. The performance testing as described in ANSI S3.45 confirms agreement of quantitative measurements between subject and predicate device.</td></tr>
</table>

	<table><tr><td>Ocular Counter Roll</td><td></td><td>•</td></tr><tr><td>VORTEQ AHR</td><td></td><td>•</td></tr><tr><td>VORTEQ vHIT</td><td></td><td>•</td></tr><tr><td>Dynamic Visual Acuity</td><td></td><td>•</td></tr><tr><td>Lateral Head Roll</td><td></td><td>•</td></tr></table>		
Video Recording and Playback Capability	Yes	Yes	Same
System Interface	A computer interface that allows for display of both eyes on computer monitor and provides power for the infrared video cameras and the LEDs	The complete system is operated from a standard PC/Laptop via a standard USB connection. The PC application software controls the camera recordings and shows the results of the tests.	Same

Performance Data Non-Clinical Tests:

- ANSI AAMI IEC ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- IEC 62304:2006+AMD1:2015, Medical device software - Software life cycle processes, Ed.1.1

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- ISO 14971:2019, Medical devices - Application of risk management to medical devices
- IEC 62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices
- ISO10993-1, Fifth edition, 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62471 First edition 2006-07, Photobiological safety of lamps and lamp systems
- ANSI/ASA S3.45-2009, American National Standard Procedures for Testing Basic Vestibular Function

Evaluation was completed following above standards and documents. Conformity to these standards demonstrates that the proposed subject device met the standards' established acceptance criteria for the device. This supports substantial equivalence to its predicates.

Clinical Performance Testing

A performance comparison test was conducted to support the substantial equivalence of the subject device. For this test, two experienced healthcare professionals (Evaluators) were recruited to evaluate the vestibular functions of 10 subjects using both the subject device and a legally marketed device (predicate device).

During the test, each subject underwent one round of testing with the subject device and another round of testing with the predicate device. The evaluators were responsible for observing the eye movements, generating test reports for each vestibular function test, and comparing the results between the two devices. The data analyzer utilized the Deming regression method (95% CI) to analyze and plot the data for comparison. The evaluators then assessed and rated the "Pass/Fail" status for all criteria of all tested subjects, including the calibration ability, eye movement direction, and Deming regression results. The test results successfully met all pre-specified acceptance criteria, demonstrating the equivalent performance between the subject device and the predicate device.

Description	**Equivalence**
Calibration	same
Spontaneous nystagmus	same
Gaze	same
Saccade	same
Pursuit	same
Optokinetic	same
Positional	same

Conclusion: The verification and validation testing, NeuroSwift Pro meets the pre-specified acceptance criteria, that are considered essential for its intended use and is considered substantially equivalent to the predicate device.