December 9, 2019

BlinkTbi Inc.
% Sonali Mathur
Regulatory Consultant
635 Rutledge Ave, Suite 102
Charleston, South Carolina 29403

Re: K191700
Trade/Device Name: EyeStat
Regulation Number: 21 CFR 882.1880
Regulation Name: Evoked Response Mechanical Stimulator
Regulatory Class: Class II
Product Code: GZP
Dated: November 6, 2019
Received: November 7, 2019

Dear Ms. Sonali Mathur:

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)*
K191700

Device Name
EyeStat

Indications for Use *(Describe)*
The EyeStat is intended to measure and display the mechanically induced blink reflex. The device is intended to be used by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under the direct supervision of a medical professional.

The device is available for use on any patient as determined by the medical professional including adults and children.

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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Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant Information:

Date Prepared:	November 5, 2019
Name:	BlinkTbi Inc.
Address:	635 Rutledge Ave., Suite 102 Charleston, SC 29403
Contact Person:	S Mathur, Consultant smathconsulting@gmail.com

Device Information:

Trade Name:	EyeStat
Common Names:	EyeStat
Classification Name(s):	Evoked Response Mechanical Stimulator
Product Code/ Regulation:	GZP / 21 CFR 882.1880
Classification:	Class II

Predicate Device:

- Nihon Kohden MEB-2300A Neuropack Evoked Potential and EMG Measuring System (K120397)

Reference Device:

- American Optical 12415 AO Non-Contact Tonometer (K802419)
- Somatosensory Stimulus System (K913604)

Device Description:

The operating principle of the EyeStat device is that the application of a light puff of air (sterile food grade CO_2) to the outer canthus of the eye acts as a stimulus that elicits a blink reflex. The puff of air is delivered while the patient's eyes are positioned within an eyepiece that allows the movement of the eye lid to be tracked using two high-speed cameras. The device uses software to evaluate the video frames containing the movement of the eyelid of the eye to which the puff of air was applied (ipsilateral) and detect the frame containing the initiation of a blink using image/video processing algorithms. The time associated with the video frame containing the initiation of the ipsilateral blink is then compared to the time associated with the application of the puff of air, and the difference represents the latency.

Indications for Use:

The EyeStat is intended to measure and display the mechanically induced blink reflex. The device is intended to be used by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under the direct supervision of a medical professional.

The device is available for use on any patient as determined by the medical professional including adults and children.

Summary Comparison to Predicate:

The following tables provide a summary of substantial equivalence between the subject device and the cited predicate. The subject device has the same intended use and substantially equivalent characteristics that do not raise different questions of safety or effectiveness.

Comparison to Predicate Device:
The following table provides a comparison of the detection features of the EyeStat device and the predicate device:

Features	BlinkTbi EyeStat	Nihon Kohden MEB-2300A Neuropack (K120397)	Comparison
General Characteristics			
Classification	Class II, 21 CFR 882.1880	Class II, 21 CFR 882.1870	Equivalent – The predicate device has multiple intended uses, including measuring and displaying reflex times. K913604 uses mechanical stimulus to evoke response.
Product Code	GZP	GWF	Equivalent – The predicate device has multiple intended uses, including measuring and displaying reflex response time
Intended Use	Measurement of mechanically evoked reflex response	Evoked Potential Measurement Device, EMG Measuring System, GSR Measuring Device, EEG Measuring System, and Nerve Conduction Velocity Measurement Device	Equivalent – The predicate device has multiple intended uses, including measuring and displaying reflex response time. K913604 uses mechanical stimulus to evoke response
Indications for Use	The EyeStat is intended to measure and display the mechanically induced blink reflex.	The Nihon Kohden MEB-2300A Neuropack Evoked Potential and EMG Measuring System is intended to monitor, record and display the bioelectric signals	Equivalent – The predicate device has multiple intended uses, including measuring and displaying reflex response time.

Features	BlinkTbi EyeStat	Nihon Kohden MEB-2300A Neuropack (K120397)	Comparison
	The device is intended to be used by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under the direct supervision of a medical professional. The device is available for use on any patient as determined by the medical professional including adults and children.	produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's nerve (NCV). The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). The device may be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG). The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or	K913604 uses a non-electrical stimulus to elicit a response.

Features	BlinkTbi EyeStat	Nihon Kohden MEB-2300A Neuropack (K120397)	Comparison
		operating room for continuous recording. The device is available for use on any patient as determined by the medical professional including adults and children.	
Environment of Use	Hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional	Hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.	Equivalent – the predicate device offers additional environments of use (ICU or OR), but is indicated to be used in all the environments as the subject device.
Target Population	Any patient as determined by the medical professional including adults and children	Any patient as determined by the medical professional including adults and children	Equivalent
Technological Characteristics			
Principle of Operation	Application of stimulus and measurement of latency until physiological response to stimulus	Application of stimulus and measurement of latency until physiological response to stimulus	Equivalent – both devices have the same principle of operation.
Stimulus Method	Physical – light puff of air onto the outer canthus of the eye	Electrical – mild electrical stimulus applied to the eye lid (for nerve conduction studies of the blink reflex)	Equivalent – both devices apply a stimulus to elicit a response. The specific method of stimulus is different, but this does not raise different questions of safety and effectiveness. The cited reference devices provides a scientific method to evaluate the effect of this difference on safety and effectiveness.
Stimulus Modes	Manual (i.e. single light puff of air) or Train (5 light puffs of air)	Single, Double, Train, Train series (Multi train, Number of train: 1 to 10)	Equivalent – both devices offer the user to apply single or multiple stimuli.

Features	BlinkTbi EyeStat	Nihon Kohden MEB-2300A Neuropack (K120397)	Comparison
Measurement Method	High speed camera	Surface EMG sensor	Equivalent – both devices measure the physiological response to a stimulus. The specific type of sensor used by each device varies, but this does not raise different questions of safety and effectiveness
Display	Camera feed displayed on screen during study	Sensed waveform displayed on screen during study	Equivalent – both devices display a view of the response to the stimulus.
Data Storage	Computed parameters may be saved to Cloud Portal (MDDS) for future review.	Waveforms may be printed, or permanently stored to storage medial for future retrieval.	Equivalent – Both devices offer means to review data at a later time.
Specific Reflex Measured	Blink Reflex	Motor nerve conduction, sensory nerve conduction, nerve conduction studies, repetitive stimulation, F-WAVE, H-WAVE, blink reflex, collision method	Equivalent – while the predicate device is cleared for multiple types of nerve conduction studies, it is specifically cleared for performing tests of the blink reflex, just as the subject device.
Parameters Measured	Latency, Differential Latency, Excursion, Time Under Threshold, Oscillations	Motor nerve conduction, sensory nerve conduction, nerve conduction studies, repetitive stimulation, F-WAVE, H-WAVE, blink reflex, collision method	Equivalent – both devices measure latency and differential latency. The subject device measures additional specific parameters associated with the physical movement of the eye lid, while the predicate device measures additional parameters associated with the bio-electrical response signal. This difference does not raise different questions of safety and effectiveness.

Features	BlinkTbi EyeStat	Nihon Kohden MEB-2300A Neuropack (K120397)	Comparison
Software	Yes, MODERATE Level of Concern	Yes, MODERATE Level of Concern	Equivalent – the specific software implementation varies, but this does not raise different questions of safety and effectiveness.
Alarm System	No	No	Equivalent

Summary of Performance Testing

Biocompatibility testing in accordance with ISO 10993-5 and ISO 10993-10 was performed. In addition, Electrical Safety testing and EMC testing was performed on the device in accordance to IEC 60601. The device passed all testing. The battery of the device was also shown to be safe in accordance with IEC 62133. A complete list of performance testing is provided in the table below:

Test	Test Method Summary	Results
Biocompatibility	Biocompatibility testing in accordance with ISO 10993-5 and ISO 10993-1	All patient contacting parts of the device pass biocompatibility testing.
Electrical Safety and EMC	Electrical Safety and EMC testing in accordance with IEC 60601-1 and IEC 60601-1-2:2014	Device passes Electrical Safety and EMC testing.
Battery Testing	Battery testing in accordance with IEC 62133	Battery passes testing.
Accuracy	Accuracy of eye lid tracking algorithm as compared to contours made by an expert reviewer	The eye lid tracking has been shown to be adequate as compared to contouring by an expert reviewer.
Precision	Test - retest reliability of all measurements made by the subject device	The precision of the measurements is equivalent to cleared evoked response measurement devices
Pressure of stimulus	Comparison of air pressures at various distances from the exit point of subject device against a non-contact tonometer device (reference device).	The air pressures associated with a stimulus are less than the reference device.

Software
The software in the device is a moderate level of concern. Software V&V testing has demonstrated that the device meets the applicable software requirements.

Conclusion

Based upon the intended use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the EyeStat has been shown to be substantially equivalent to the legally-marketed predicate.