March 29, 2018

Blink Device Corporation
Justin Hulvershorn
CEO
1530 Westlake Ave N Suite 600
Seattle, Washington 98109

Re: K172843
Trade/Device Name: TwitchView System
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: February 27, 2018
Received: February 28, 2018

Dear Justin Hulvershorn:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K172843

Device Name
TwitchView System

Indications for Use *(Describe)*

The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography.

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
PRAStaff@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."

Section 5 – 510(k) Summary

(As Required by 21 CFR 807.92)

General Information:

Date of Summary Preparation	February 27, 2018
Name and Address of Manufacturer	Blink Device Company 1530 Westlake Ave N Suite 600 Seattle, WA 98109
Contact Person	Justin Hulvershorn, MD, PhD Chief Executive Officer Phone: (206) 295-3372
Proprietary Name:	TwitchView System
Common Name:	Peripheral Nerve Stimulator and Monitor
Regulation Number:	§ 21 CFR 868.2775
Regulation Description:	Electrical peripheral nerve stimulator
Device Class:	II
Review Panel:	Anesthesiology
FDA Product Code:	KOI

Performance Standards:
PART 898 -- PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES applies to the device.

Device Description: The TwitchView System has been designed to provide a quantitative neuromuscular transmission monitor with a modernized user interface and a single-use electrode array that is placed on the hand of the patient. The degree of neuromuscular block is measured with the TwitchView System by stimulating a peripheral nerve (the ulnar nerve at the wrist), and by evaluating the response of the muscles in the hand via electromyography.

The TwitchView System consists of three components:

1. TwitchView Monitor
2. TwitchView Charging Station
3. Single-Use Electrode Array

TwitchView Monitor: The TwitchView Monitor contains the electronics to stimulate the nerve and also to measure the resulting EMG response. The user interacts with the TwitchView Monitor via a touch screen LCD and a Power button. The TwitchView Monitor connects to the single-use Electrode Array via an 8' cable. The Monitor also contains an inductive coil that allows the Charging Station to wirelessly charge the Monitor's lithium ion battery. Finally, the Monitor transmits neuromuscular monitoring data to the Charging Station by means of a short range (i.e. less than 6 inch) two-way infrared (wireless) communications port that functions when the Monitor is docked in the Charging Station.

TwitchView Charging Station: The TwitchView Charging Station's primary purpose is to charge the Monitor's battery. The Charging Station also receives neuromuscular monitoring data from the Monitor by means of the aforementioned infrared communications port. The Charging Station receives power from an AC to DC power adapter that plugs into a standard wall outlet. Finally, the Charging Station contains an output port, whereby the neuromuscular monitoring data received from the Monitor can be output using a combination RS232 serial and Ethernet port implemented over an industry standard RJ45 connector.

Single-Use Electrode Array: The TwitchView single-use Electrode Array is placed on a patient's wrist and hand area for the duration of device use. The Electrode Array contains five independent electrode pads – two for stimulation and three for EMG. A biocompatible hydrogel provides the interface between the patient's skin and the Electrode Array, which allows the Monitor to transmit stimulation pulses to the patient, and receive the resultant EMG signals.

Predicate and Reference Devices: The predicate and reference devices utilized for comparison to the TwitchView System to establish substantial equivalence are tabulated below.

Predicate/Reference Device	510(k)
TOF Watch (*Predicate Device*)	K972698
GE CARESCAPE B450 (*Reference Device*)	K132533
Xavant Stimpod (*Reference Device*)	K102084

A table at the end of this summary provides a summary of the technological characteristics of the TwitchView System in comparison to the predicate and reference devices.

Indications for Use: The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography.

Table 5-1: Comparison between the intended use and indications for use statements of the subject and predicate device

	TwitchView System	TOF Watch (Predicate Device)
Intended Use	Quantitative (objective) neuromuscular transmission monitoring	Same
Indications for Use	"The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography."	"The TOF Watch can be used as an objective monitor using accelerometry for measuring the muscle contraction following a stimulation of the respective motorneuron ..."

The indications for use statements for the subject and predicate device indicate that both devices are quantitative monitors (quantitative and objective are used interchangeably to indicate that the device has a movement detection element – typically to monitor thumb motion). Similarly, both devices measure neuromuscular transmission (which can be defined as "*measuring the muscle contraction following stimulation of the respective motorneuron*" as written in the predicate indications for use statement). Both devices use a constant current stimulation pulse to stimulate the peripheral nerve. However, the subject TwitchView System uses electromyography to measure the muscle response (the same method used in the reference GE Carescape device) whereas the predicate TOF Watch device uses accelerometry to measure the muscle response. In use, electromyography and accelerometry have been shown to produce clinically equivalent measures of the muscle response and therefore similar assessments of neuromuscular transmission.

As discussed above, the indications for use statement for the TwitchView System is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the quantitative monitoring of neuromuscular transmission, with the differences in indication wording primarily related to the use of electromyography (relative to accelerometry) as the means of measuring muscle contraction.

Comparison of Technological Characteristics: Both the subject and predicate devices measure the muscle response following stimulation of the related motorneuron (i.e. they monitor neurotransmission). Both devices stimulate a peripheral nerve using a constant current stimulation pulse. However, the subject device uses electromyography to measure the muscle response, whereas the predicate device uses accelerometry to measure the muscle response.

Table 5-2: Comparison between the technical characteristics of the subject device, the predicate device, and the reference devices.

	TwitchView System	TOF Watch (Predicate Device)	GE Carescape Monitor B450 (Reference Device)	Xavant Stimpod NMS450 Nerve Stimulator (Reference Device)
Intended Use	Quantitative (objective) neuromuscular transmission monitoring	Same	Same	Same
Stimulation	Constant current, monophasic, square wave pulse	Same	Same	Same
Muscle Response Detection	Electromyography	Accelerometry	Electromyography	Accelerometry

Electromyography directly measures the electrical activity generated during muscle contraction. Specifically, electromyography measures the integrated area under the waveform curve (or the peak-to-peak amplitude) of the evoked muscle action potential to measure the size of the evoked response. Accelerometry is based on Newton's second law of motion (force = mass × acceleration). Since the mass of the thumb remains constant, acceleration is directly proportional to force. For measurement of acceleration, a piezo-electric wafer is fixed to the thumb. When the thumb moves because of nerve stimulation, an electrical signal is produced in the piezoelectric crystal that is proportional to the thumb acceleration. Both electromyography and accelerometry result in a measurement of the size of the muscle response following nerve stimulation, and both methods have been shown to provide clinically similar measurements of neuromuscular transmission (as indicated in the table above for the TwitchView System and the cited predicate and reference devices).

Summary of Testing:
The essential requirement of the primary functions of the subject device, namely to stimulate a peripheral nerve and to measure the resultant muscle response via electromyography, are governed by the **IEC 60601-2-40 Standard: Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment**. Additionally, **PART 898 -- PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES** applies to the device. Testing demonstrated that the requirements of both standards have been met, thus supporting the substantial equivalence of the subject device for it intended use.

In addition, to further demonstrate intended device performance, as well as to support the substantial equivalence, the performance and technological characteristics of the TwitchView System were evaluated by completion of the following testing:

- Package Testing
- Shelf Life (Electrode Array)
- Monitor and Charging Station Expected Service Life
- Biocompatibility (<24 hour contact with intact skin) in accordance with ISO10993-1
    - Cytotoxicity
    - Sensitization
    - Skin Irritation
- Software Verification and Validation in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- Electrical Safety in accordance with IEC 60601-1
- Electromagnetic Compatibility in accordance with IEC 60601-1-2
- Electromagnetic Interference
- Bench Performance Testing
    - Stimulation Accuracy
    - Electromyography Accuracy
    - Battery Life
    - Electrode Array to Monitor Connection
    - Conductivity of Electrode Array
    - Electrode Array to Monitor Cable Removal Force
    - Electrode Array Duration of Usability
    - Applicable Testing per ANSI/AAMI EC12: 2000/(R)2015 for Disposable ECG Electrodes
    - Resistance of Electrode Array to Spillage
    - Durability of Electrode Array Connector Clip
    - Maximum Operating Temperature (Electrode Array)

The results from this testing:

- support the substantial equivalence of the TwitchView System that is the subject of this 510(k), and
- ensure the TwitchView System can perform in a manner equivalent to the predicate device with the same intended use.

Conclusion (Statement of Equivalence):

Table 5-3 provides an overall summary of the predicate basis for the TwitchView System. The data and information presented within this submission (including *in vitro* bench testing) support a determination of substantial equivalence, and thereby support the market clearance of the subject Blink Device Corporation TwitchView System under this 510(k) Premarket Notification.

Table 5-3: Predicate/Reference Substantial Equivalence Basis Summary

Design/Technical Characteristic	TwitchView System	TOF Watch (Predicate Device)	GE Carescape Monitor B450 (Reference Device)	Xavant Stimpod NMS450 Nerve Stimulator (Reference Device)
Regulatory History	New device	K972698	K132533	K102084
Classification Panel	Anesthesiology	Same	Same	Same
Classification Name	Electrical peripheral nerve stimulator.	Same	Same	Stimulator, Nerve, Battery-Powered
Device Class	Class II	Same	Same	Same
Device Code	KOI	Same	Same (secondary product code)	BXN
Intended Use	Quantitative (objective) neuromuscular transmission monitoring	Same	Same	Same
Indication for Use	"The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography."	"The TOF Watch can be used as an objective monitor using accelerometry for measuring the muscle contraction following a stimulation of the respective motorneuron ..."	"The CARESCAPE Monitor 8450 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility. The CARESCAPE Monitor B450 is indicated for monitoring of … neurophysiological status (including … neuromuscular transmission)."	"This product is a nerve stimulation device designed to be used by an anesthetist during: 1. General Anaesthesia,for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes (not supplied) …"
Stimulating Current Range	0-80 Ma	0-60Ma	0-70mA	0-80 mA
Muscle movement detection technology	Electromyography	Acceleromyography	Electromyography	Acceleromyography
Primary Stimulation Sequences	Train of Four Post Tetanic Count Single Twitch Tetanus Calibration sequence	Same	Same	Same
Electrode Contacts for Stimulation	Single use electrode array	Reusable wires attach to standard ECG electrodes (not part of device)	Reusable wires that attach to standard ECG electrodes (not part of device)	Reusable wires that attach to standard ECG electrodes (not part of device)
Apparatus for electromyography/ acceleromyography	Single use electrode array	Reusable accelerometer secured to patient's thumb	Reusable wires that attach to standard ECG electrodes (electrodes are not part of device)	Reusable accelerometer secured to patient's thumb