June 22, 2020

Byteflies NV
% Benjamin Vandendriessche
Chief Medical Officer
MedicSense USA
Borsbeeksebrug 22, 6th Floor
Berchem
Antwerpen, BEL 2600

Re: K192549
Trade/Device Name: Byteflies Kit
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC
Dated: March 27, 2020
Received: March 31, 2020

Dear Benjamin Vandendriessche:

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,

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

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)*

K192549

Device Name
Byteflies Kit

Indications for Use *(Describe)*

The Byteflies Kit is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, and transmit electrical activity of the brain by placing non-invasive electrodes on the head of patients. It acquires, records and transmits two channels of electroencephalogram (EEG) data. The medical use of data acquired by the Byteflies Kit is to be performed under the direction and interpretation of a licensed medical professional. The Byteflies Kit does not provide any diagnostic conclusions about the patient's condition.

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

Contact Details

Applicant	Byteflies NV Borsbeeksebrug 22, 6th floor 2600 Berchem Belgium Tel: +32 32 94 74 99
Contact Person	Benjamin Vandendriessche, PhD Chief Medical Officer benjamin.vandendriessche@byteflies.com +1 (216) 777-9234
Date Prepared	March 25, 2020

Device Name

Trade Name	Byteflies Kit
Common Name	EEG Monitor
Classification	Reduced-Montage Standard Electroencephalograph (Class II)
Product Code	OMC
Regulation Number	21 CFR 882.1400

Predicate Device

NeuroWave Systems Inc, DiscoverEEG System, Model DE-401 (K142834, product code: OMC)

Description of Device

The Byteflies Kit is a wearable medical device for continuous recording of non-invasive physiological signals in healthcare and home settings. The Byteflies Kit is intended to be configured by a trained healthcare professional and consists of 3 main components:

1. Sensor Dot: a biopotential wearable sensor that measures up to 2 bipolar channels of electroencephalography (EEG). It is powered by a rechargeable battery, can record data for up to 24 hours on a single charge, and has an LED indicator to report the operating

status to the user. The sample-level EEG data is continuously stored on the Sensor Dot for later retrieval.

2. Sensor Patch: the interface between a Sensor Dot and non-invasive biopotential electrodes (not provided). It attaches magnetically to the Sensor Dot and has four DIN 42802 connectors. Two commercial disposable EEG electrodes per Sensor Patch channel are connected to the head of the subject in a reduced EEG montage. The Sensor Dot attached to the Sensor Patch is carried by the patient to continuously measure electrical brain activity.
3. Docking Station: up to 5 Sensor Dots can connect magnetically to the Docking Station and transfer recorded data to the Docking Station, while charging their batteries. The recorded sample-level EEG signals can then be downloaded from the Docking Station's Management Interface to a computer via a local WiFi network for long-term storage and further review by a healthcare professional. An AC/DC adapter with micro-USB cable supplies power to the Docking Station.

Intended Use

The Byteflies Kit is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, and transmit electrical activity of the brain by placing non-invasive electrodes on the head of patients. It acquires, records and transmits two channels of electroencephalogram (EEG) data. The medical use of data acquired by the Byteflies Kit is to be performed under the direction and interpretation of a licensed medical professional. The Byteflies Kit does not provide any diagnostic conclusions about the patient's condition.

Substantial Equivalence Comparison

The Byteflies Kit is technologically equivalent to other EEG monitoring devices. Both the Byteflies Kit and the predicate device are wearable devices that acquire analog EEG signals in a reduced montage, digitize the sample-level signal, and save them for later interpretation by a healthcare professional. Based on the results from our extensive testing, we believe that our device does not raise new safety or efficacy concerns. The table below summarizes the technological characteristics of the Byteflies Kit in comparison to the predicate device.

Features and Characteristics	Byteflies Kit (subject device)	DiscoverEEG System (predicate device)	Comparison
Indications for Use	The Byteflies Kit is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, and transmit physiological signals from patients. It acquires, records, and transmits two channels of electroencephalogram (EEG) data, that are intended to be reviewed by a trained healthcare professional. It only acquires these signals; no diagnostic claims are made about the patient's condition.	The DiscoverEEG System, Model DE-401 is intended to be used for measuring and recording the electrical activity of a subject's brain, obtained by placing noninvasive electrodes on the head. The DiscoverEEG DE-401 is indicated for use in acquiring electroencephalographic (EEG) signals in the OR, ICU, ER, clinical settings and at home and for clinical research. The medical use of data acquired by the DiscoverEEG is to be performed under the direction and interpretation of a licensed medical professional. The DiscoverEEG DE-401 does not provide any diagnostic conclusion about the subject's condition.	Signal Type: EQUIVALENT Both devices record a reduced EEG montage via noninvasive electrodes placed on the head Environment: EQUIVALENT Both devices are indicated for use in home, clinical, and research environments Medical Use: EQUIVALENT Both devices record raw EEG data and make this available to a healthcare professional for further interpretation; neither device provides any diagnostic claims about the subject's condition
Modalities	EEG	EEG	EQUIVALENT
Environment of Use	Home (data acquisition), Healthcare and Clinical Research Facility (data acquisition, device configuration, and data retrieval).	Operating room, intensive care unit, emergency room, clinical settings and at home where EEG monitoring is used.	EQUIVALENT
Power Source	Li-Ion battery (Sensor Dot) and a certified Class	Battery	EQUIVALENT The components of both devices that are carried

	II AC/DC power supply (Docking Station)		by the patient are battery powered. The Docking Station for the subject device is powered via the included certified Class II power supply; this difference does not raise questions of safety and efficacy as the Docking Station does not have any AC wiring and was subjected to all applicable electrical safety testing.
System Components	Sensor Dot, Sensor Patch, Docking Station	Electrode (Sensor) Array, Acquisition and Memory Modules, Data Viewer Software	EQUIVALENT Both devices consist of equivalent system components for connecting to noninvasive EEG electrodes, storing, and retrieving data. One difference exists: the Byteflies Kit provides charging and data retrieval functionality via the Docking Station, which is separate from the main wearable device (Sensor Dot) to keep the latter's size and weight down. This is a usability decision that does not raise questions of safety and efficacy.
Sensing Electrodes	User-supplied disposable EEG electrodes	Silver-silver chloride disposable EEG electrodes	EQUIVALENT Both devices use disposable noninvasive biopotential electrodes. The Byteflies Kit does not include them as part of the device but uses FDA

			cleared DIN 42802 EEG electrodes as accessories which provides more flexibility to the user. This is a usability decision that does not raise questions on safety and efficacy.
Screen Display Details	Not applicable	Data Viewer Software	EQUIVALENT The Byteflies Kit contains no data viewer software although data files can be imported into any signal review software that can read and visualize EEG data, as is the case for the predicate device.
Stored EEG data available	Sample-level EEG as text file which can be accessed via the Docking Station	Yes – SD card	EQUIVALENT Sample-level EEG data can be downloaded to a computer for long-term storage and further analysis by a trained healthcare professional.
EEG Channels	Up to 2 EEG channels	Up to 4 EEG channels	EQUIVALENT
Contains patient isolation	Sensor Dot is battery powered, thus no connection between patient and mains. The Docking Station is powered by a certified Class II AC/DC medical power supply and contains now AC wiring.	Battery powered, thus no connection between patient and mains.	EQUIVALENT The components of both devices that are carried by the patient are battery powered. The Docking Station for the subject device is powered via the included certified Class II power supply; this difference does not raise questions of safety and efficacy as the Docking Station does not have any AC wiring and was subjected to all

			applicable electrical safety testing.
Display Interface	Yes, LEDs to ensure proper system connection and operation.	Yes, LEDs to ensure proper system connection and operation.	EQUIVALENT
Biocompatibility	All external parts were tested according to ISO 10993 (Cytotoxicity – ISO 10993-5, Sensitization – ISO 10993-10, and Skin Irritation – ISO 10993-10)	Electrode array was tested according to ISO 10993 (Cytotoxicity – ISO 10993-5, Sensitization – ISO 10993-10, and Skin Irritation – ISO 10993-10); test status for other components unknown	EQUIVALENT All external parts of the Byteflies Kit meet the requirements of ISO 10993.
Electrical Safety and Electromagnetic Compatibility	IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-1-8, IEC60601-1-6, IEC60601-2-26	IEC60601-1, IEC60601-1-11, IEC60601-2-26, IEC60601-1-2	EQUIVALENT The Byteflies Kit was subjected to the same electrical safety and electromagnetic compatibility testing as the predicate device, and was additionally verified against 60601-1-6 and 60601-1-8.
510(k) #	K192549	K142834	NA
Regulatory	Product Code OMC 21 CFR 882.1400	Product Code OMC and OLT 21 CFR 882.1400	EQUIVALENT Both devices use the same product code, but the Byteflies Kit does not include any EEG viewing software; this difference does not raise questions on safety and efficacy as both devices allow 3rd party signal viewers to be used.

Non-clinical Testing

Design and verification tests were performed on the Byteflies Kit as a result of the risk analysis and product requirements. Independent UL-certified laboratory testing demonstrated that the Byteflies Kit meets the requirements of IEC 60601-1:2005 and IEC 60601-1-11:2015 for electrical safety, and IEC 60601-1-2:2014 for electromagnetic compatibility. The Byteflies Kit complies with the particular requirements of IEC 60601-2-26:2012 for the safety of electroencephalographs. Finally, it meets all applicable requirements of ISO 10993:2018, IEC 60601-1-6:2010 and IEC 60601-1-8:2006.

Clinical Tests

The Byteflies Kit is an electroencephalographic device comprised of hardware and software that has been bench tested to assess safety and effectiveness, and to establish substantial equivalence with the predicate device. We believe further clinical data is not required to demonstrate performance of the Byteflies Kit for the indications for use subject to this submission.

Conclusion

Based on the results of the performance testing and substantial equivalence comparison, the Byteflies Kit has the same intended use and principles of operations as the predicate device. Any differences in technological characteristics do not raise questions about safety and effectiveness. The presented information is sufficient to determine that the Byteflies Kit is substantially equivalent to the legally marketed predicate device.