November 9, 2021

Pamel d.o.o
% Stefan Bolleininger
CEO
be-On-Quality GmbH
Bahnhofstrasse 85
Neunkirchen am Sand, D-91233 DE

Re: K211315
Trade/Device Name: Comby EEG Caps
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 13, 2021
Received: October 13, 2021

Dear Stefan Bolleininger:

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211315

Device Name
Comby EEG Cap

Indications for Use *(Describe)*
The Comby EEG Cap is intended for use in routine clinical settings where rapid placement of large number of EEG electrodes is desired.

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 OR 510(K) STATEMENT

5.1 Applicant

Date: 21-04-2021

Name: **Pamel d.o.o.**

Address: Mesekov put 16, 10000, Zagreb, Croatia

Contact Person in Germany: **Stefan Bolleininger**

Telephone: +49 9131 977986 – 50
Fax: +49 9131 977986 – 449
E-Mail: stefan.bolleininger@be-on-quality.com

Signature: _____

5.2 Trade Name : Comby EEG Cap

5.3 Common Name or Classification Name Disposable EEG Electrodes system

5.4 Establishment Registration Number

Not registered

5.5 Facility Address : Pamel d.o.o.

Mesekov put 16, 10000, Zagreb, Croatia

5.6 Device Classification

5.6.1 Classification: This is a class II device

5.6.2 Classification panel: Cutaneous electrodes

Product code: GXY

5.7 Regulation Number 21 CFR 882 1320

5.8 Predicate Devices Descriptions

Predicate device 1	Predicate device 2	Predicate device 3
Electro-Cap System Electrode Arrays (Predicate) 510(k) #K112319	Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP DEVICE K200162	Wave Guard Eemagine Medical (Predicate) 510(k) #K110223
Electro-Cap International Inc 011 W Lexington Rd, Eaton, OH 45320, United States	Wuhan Greentek Pty Ltd. Rm 03-2, Flr. 3, Dingye Bldg, Phase, Wuhan CN 430074	EEMAGINE MEDICAL IMAGING SOLUTIONS GMBH 8870 RAVELLO CT Naples, FL 34114

5.9 Proposed Device Description

The Comby EEG Cap is an electrode positioning system used to quickly place the standard 20 EEG electrodes or more in a uniform and consistent manner on the head and body in order to transmit electrophysiological signals from an individual to data collection devices. The Comby EEG Cap is made from high quality profile rubber net, electrode plastic holders made of SEBS and electrodes. Electrodes is made of two different conductors, sintered Ag/AgCl and gold coated plates. The EEG Comby Cap is fixed by Velcro tape holders which are fastened beneath the chin of the tested person. The cap holders is fixed to a belt, placed beneath the arms and around the chest of the tested person. The high quality profile rubber net holds the electrodes securely in position during the EEG recording. Wires are attached to each electrode and exit the cap to form a cable, which is used to connect the cap to the EEG equipment, either through an adapter cable, or directly to the equipment with the 25-pin D-sub connector. The electrical activity of the brain is transferred through the conductive Electro-Gel/paste to the recessed electrode and then to the EEG or computer equipment for evaluation. The electrodes on the standard caps are positioned in

accordance with the International 10-20 System of electrode placement. In addition, the Comby EEG Cap with as few as 2 to as many as 64 electrodes. Comby EEG are also produced based on customer specified electrode placements, with electrodes made of Ag/AgCl material. Customized wiring and connectors offer additional options.

The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin "Electroconductive gel is a legally marketed product in US - K111717" information "Company Name: Electra-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320 Contact: Amy Swallows Phone: 937-456-6099 Fax: 937-456-7323 Trade Name: Electra-Gel Common Name: Electrode Gel.

5.10 Indications for Use Statement

The Comby EEG Cap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.

5.11 Required Components

The Comby EEG Cap needs to be used with conductive gel or paste (such as Electro-Gel), EEG device **and** computer equipment for evaluation.

5.12 Bench Testing

The COMBY EEG CAP was tested for performance in order to verify compliance according to the following technical specifications and standards: ANSI/AAMI EC12:2000 (R2015) Disposable ECG Electrodes. Results indicate that the product complies with the applicable standard.
The release test is also conducted on the product when it leaves the facility and the Performance release record is available in section 18. Compare to primary predicate devices specified and Comby EEG cap are same in, raw materials, physical features, and same manufacturing processes. The biocompatibility performance equiva- lence evidence of proposed electrode can be demonstrated according to ISO10993-1, ISO10993-5 and ISO10993-10.
Clinical Data: Clinical testing is not required

Non clinical data:Non clinical tests performed include
Performance test :We performed electrical safety. The design of the Comby EEG cap is in conformance with performance in order to verify compliance according to the following technical specifications and standards: ANSI/ AAMI EC12:2000 (R2015) Disposable ECG Electrodes.

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Styrene-ethylene-butylene-styrene, also known as SEBS, is an important thermoplastic elastomer (TPE) which behaves like rubber without undergoing vulcanization. Mounts made of SEBS provide an effective hold of the electrodes in the position without producing any pressure around the muscles. Muscle pressure artifacts are very common in EEG recording, and should be minimized to achieve the best recording result. SEBS electrode mounts are also more comfortable for the patient.

Comby EEG Caps have shorter cables when compared to the predicates. Shorter cables create less artifacts during the recoding form the environment, it is used on purpose to get better results as the recording can be made closer to patient without any environmental disturbance.

In COMBY EEEG CAP, maximum of 64 electrodes are required to provide coverage for the complete scalp.
The stated differences are made in the purpose of improving the EEG recording quality and patient comfort. Therefore COMBY EEG cap performs minimally as well or better that the predicates.

All the differences do not affect the safety and effectiveness of the subject device which is concluded after all the required testing, so there are no safety and effectiveness issues relating to the subject system.

Clinical testing is not required

We performed electrical safety. The design of the Comby EEG cap is in conformance with performance in order to verify compliance according to the following technical specifications and standards: ANSI/AAMI EC12:2000 (R2015) **Disposable ECG Electrodes.**
Biocompatibility: 1. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 2. ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity 3. ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Conclusion- Based on the comparison with predicate device, our Comby EEG cap has the same intended use, structure, and technologies, which is substantially equivalent to predicated device.

5.13 Summary table of comparison

Predicate Comparison Chart -Table 1

Feature	Subject device	Predicate device	Predicate device	Predicate device	Discussion
510(k) Number		K112319	K200162	K110223	
Indication for Use	The Comby EEG is intended for use in routine clinical settings where rapid placement of a large number of EEG electrodes is desired	Electro-Cap System Electrode Arrays The Electro-Cap is intended for use in routine clinical set-tings where rapid placement of a large number of EEG	Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is de-sired.	This is an EEG electrode set intended for use in routine clinical settings where rapid placement of a large number of EEG electrodes is de-sired	Same
Classification	Class II	Class II	Class II	Class II	Same
Regulation number	21CFR882.1320	21CFR882.1320	21CFR882.1320	21CFR882.1320	Same
Regulation	cutaneous electrode	cutaneous electrode	cutaneous electrode	cutaneous electrode	Same
Product code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	Same

Environment of use	Electrophysiological	Electrophysiological	Electrophysiological	Electrophysiological	Same
Intended user	Neurologists	Neurologists	Neurologists	Neurologists	Same
Target patient	Adults and Children	Adults and Children	Adults and Children	Adults and Children	Same
Where used	On the head	On the head	On the head	On the head	Same
Number of contacts	2-64	2-256	2-128	1-256	provide better recording and patient comfort
Size of Caps	Various- Babies to Large 27cm-62cm	Various- Babies to Large 26cm-66cm	Various- Babies to Large 26cm-66cm	Various- Babies to Large 25cm-61cm	Same
Style of Caps	Full head cap	Full head cap	Full head cap	Full head cap	Same
Ear Slits	yes	yes	yes	yes	Same
Cap material	High Quality Profile Rubber	Spandex	Spandex	Elastic Coolmax	equivalent

Elec-trode Mounts	SEBS	Polyethylene	Silicone	Silicone	The electrode mounts- base is made of comfort-able SEBS plastic. SEBS behaves like rubber but is artificial, and the electrode holders have rounded corners so that they are easy to handle and non-invasive on the skin.
Cable Length	2-5 Feet	Various- 3-5 feet	0.1m – 3.0m	Not Available	does not effect safety
Type of Cables	Standard ribbon cable and lead wires		Standard rib-bon cable and lead wires	Shielded Lead Wires	Same

Electrode Metal	Ag/AgClAg CL sintered material Gold plated pure 99% Silver	Pure Tin, Silver, Silver/Silver-Chloride, Gold plated	1. FLEX-CAP: silver/silver chloride ink printed electrodes on PET (Polyethylene terephthalate) 2 DL and E-CAP silver /silver chloride plated ABS base	Silver/Silver/Chloride	Same as predicate
Type of connectors	D-Sub Connectors 25-in and 37-pin, Touch Proof Din Sockets and Special Connectors to Match EEG Equipment & Computers	D-Sub Connectors, Touch Proof Din Sockets and Special Connectors to Match EEG Equipment & Computers	Touch-proof safety socket DIN42-802 (Φ=1.5mm)	D-Sub Connectors 25 and 35 pins.	Same as the predicate device
Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10	None was Conducted	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1, ISO 10993-5, ISO 10993-10	The subject device has been tested for biocompatibility according to the FDA guidance, this difference does not raise any new safety or effectiveness.

Performance requirements	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	1. Resistance <100 Ω 2. AC impedance <2 kΩ (at 10 Hz) 3. DC offset voltage <100 mV 4. Combined offset instability and internal noise: <150 µV 5. Bias current tolerance <100 mV	Needs to transmit electrophysiological signals from an individual to data collection de-vices with a maximum impedance of 5K/Ohms. Does not transmit electrical cur-rent, nor are they intended to be used for stimulation.	Performance of the Comby EEG cap is tested as per **ANSI/AAMI EC12:2000(R 2015) Disposable ECG Electrodes**