February 1, 2018

Micromed S.p.A
% Joseph Ouellette
Senior Consultant
EAS Consulting Group
1700 Diagonal Road Suite 750
Alexandria, Virginia 22314

Re: K171384
Trade/Device Name: Micromed BRAIN QUICK System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: January 2, 2018
Received: January 2, 2018

Dear Mr. Ouellette:

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. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K171384

Device Name
Micromed BRAIN QUICK system

Indications for Use *(Describe)*
The Micromed BRAIN QUICK system is intended to acquire and store physiological signals for EEG and/or polysomnography (PSG) and to transfer data to separate PSG analysis software.

The system includes:
-hardware recorders intended to acquire and temporarily store physiological signals for EEG and/or PSG and to transfer the data to separate polysomnographic analysis software, and
-software which is used for the signal acquisition, display, storage, process and measure of biologic signals.

The hardware recorders (amplifiers) are BRAIN SPY PLUS, MORPHEUS, SD LTM 32 EXPRESS and SD LTM 64 EXPRESS. They are intended to acquire the same kind of signals by using the SystemPlus EVOLUTION software. The recorder models differ based on the number of available EEG channels (16 in the BRAIN SPY PLUS, 24 in the MORPHEUS, 32 in SD LTM 32 EXPRESS and 64 in SD LTM 64 EXPRESS). A system with up to 256 channel can be obtained by cascading 4 SD LTM 64 EXPRESS amplifiers.

The device is intended to be used by physicians, technicians, and other medical professions that are trained in EEG and/or PSG.

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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K171384 510(k) Summary

SUBMITTER

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Date Prepared: January 31, 2018

SUBJECT DEVICE

Trade Name:	Micromed BRAIN QUICK System
Common or usual names:	Electroencephalograph
Proprietary name:	BRAIN QUICK
Classification name:	Electroencephalograph (21 CFR 882.1400)
Regulatory Class:	II
Product Code:	GWQ, OLV

PREDICATE DEVICE

The predicate devices used in this submission are:

- **K122196** Blackrock NeuroMed Cervello Bio-Potential Signal Acquisition System–Basic
- **K071782** MICROMED MORPHEUS, MICROMED BRAIN SPY PLUS

DEVICE DESCRIPTION

The Micromed BRAIN QUICK System is a multi-modal physiological recording system, for use in research institutions, clinics, hospitals, operating rooms, epilepsy monitoring unit environments and/or sleep laboratories. The Micromed BRAIN QUICK System is a modular system which can be configured in different versions; however, the intended use, operating principle and technology remain the same for the different configurations of the Micromed BRAIN QUICK system. The basic unit consists of one or more acquisition amplifiers, a communication interface for transferring data to a PC, a PC with monitor and user interface devices and software for the processing, storage and display of the acquired traces. The power supply is provided through an isolation transformer allowing the connection of several devices to the transformer secondary winding.

The Micromed BRAIN QUICK system acquires EEG signals (bio-potential derived from the brain activity) from third-party commercial electrodes connected to the patient. The Micromed BRAIN QUICK system processes the signal (amplification and filtering), converts it from analogical to digital representation and transmits the result to the software which controls the display of the resulting signal on a monitor, the storage of the

signal on a digital storage media (e.g. hard disk or DVD), the analysis for deriving signal measures. The clinical meaning of the displayed trace is determined by the physician only, based upon the signal morphology.

The device is not intended to directly come in contact with any part of the patient body. The device uses and is compatible with EEG commercial electrodes. The device is neither sterile nor sterilizable. It is reusable. The expected lifetime is ten years.

Intended use, users, environment and indications for use are reported in the intended use section of this 510(k) Summary.

Key Performance Specifications and Characteristics of the Device are reported in the comparison to predicate devices section of this 510(k) Summary.

INTENDED USE

The Micromed BRAIN QUICK System is intended to record, display, store and archive bio-potential signals. It can do this wireless via Class I Bluetooth or via cables.

The Indications for Use statement for the Micromed BRAIN QUICK system is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relevant to the predicate:

- The Micromed BRAIN QUICK System has overall the same intended use in the same environments as the predicate device.

- Both the Micromed BRAIN QUICK System and the predicate have the same intended use for the recording, display and storage and archiving of bio-potential signals.

- The Micromed BRAIN QUICK system IFU has been reworded in order to highlight the presence and functions of the software.

	Micromed BRAIN QUICK (Subject Device)	**Blackrock NeuroMed Cervello Basic Bio-Potential Signal Acquisition System** **K122196**	**Micromed Morpheus, Brain Spy Plus** **K071782**
Intended Use	The Micromed BRAIN QUICK system is intended to record, display, store and archive bio-potential signals.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array and user-specified locations.	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user specified locations.
Intended Use Environment	Research institutions, clinics, hospitals, operating rooms, epilepsy evaluation unit environments or sleep laboratories.	Not stated	Medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional
Target Patient Population	Adult and pediatrics	Not stated	The device will be available on all patient populations as determined by a trained professional

	Micromed BRAIN QUICK (Subject Device)	**Blackrock NeuroMed Cervello Basic Bio-Potential Signal Acquisition System** **K122196**	**Micromed Morpheus, Brain Spy Plus** **K071782**
Indications for Use	The Micromed BRAIN QUICK system is intended to acquire and store physiological signals for EEG and/or polysomnography (PSG) and to transfer data to separate PSG analysis software. The system includes: -hardware recorders intended to acquire and temporarily store physiological signals for EEG and/or PSG and to transfer the data to separate polysomnographic analysis software, and -software which is used for the signal acquisition, display, storage, process and measure of biologic signals. The hardware recorders (amplifiers) are BRAIN SPY PLUS, MORPHEUS, SD LTM 32 EXPRESS and SD LTM 64 EXPRESS. They are intended to acquire the same kind of signals by using the SystemPlus EVOLUTION software. The recorder models differ based on the number of available EEG channels (16 in the BRAIN SPY PLUS, 24 in the MORPHEUS, 32 in SD LTM 32 EXPRESS and 64 in SD LTM 64 EXPRESS). A system with up to 256 channel can be obtained by cascading 4 SD LTM 64 EXPRESS amplifiers. The device is intended to be used by physicians, technicians, and other medical professions that are trained in EEG and/or PSG.	Up to 64 channels with one Cervello hardware device (Amplifier) and up to 128 channels by cascading 2 Cervello devices using the Cervello software. The device is intended to acquire and store physiological signals for EEG and/or PSG, and to transfer the data to separate polysomnographic analysis software. The devices are intended to be used by physicians, technicians and other medical professions that are trained in EEG and/or PSG. The Cervello Basic System does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.	Acquire and store physiological signals for EEG and Sleep Studies, and to transfer the data to separate polysomnographic analysis software. The devices are intended for use by physicians, technicians, or other medical professionals that are trained in EEG and/ or PSG.
Use limitations	The BRAIN QUICK system does not make any judgment of normality or abnormality of the displayed signals or the result of an analysis. In no way are any of the functions represented as being in themselves diagnostic. Moreover, the system is not a monitoring system: no physiologic alarms are provided.	The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician. The devices do not make any judgment of normality or abnormality of the displayed signals.	. These devices do not provide alarms and is not intended for use as an automated apnea monitor. The devices do not make any judgment of normality or abnormality of the displayed signals.
Bio-Potential Signals	Electroencephalography (EEG), Video EEG, Respiration, Heart	Electroencephalography (EEG) VideoEEG, Respiration, Heart Rate,	Electroencephalography (EEG)

	Micromed BRAIN QUICK (Subject Device)	**Blackrock NeuroMed Cervello Basic Bio-Potential Signal Acquisition System K122196**	**Micromed Morpheus, Brain Spy Plus K071782**
Recorded	Rate, SPO2	SPO2	Electrocardiography (ECG) Respiration, Heart Rate, SPO2
Potential Clinical Applications	Bio-potential signal acquisition: amplification, recording, digitization, display and storage.	Bio-potential signal amplification, recording, display, digitization, retrieval and display.	The device function is the acquisition of bioelectric signals, as is typical for EEG amplifiers and Holter recorders.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

As shown in the following table, the BRAIN QUICK system shares similar technological characteristics with the predicates the main technological characteristics.

	Micromed BRAIN QUICK (Subject Device)	**Blackrock NeuroMed Cervello Basic Bio-Potential Signal Acquisition System K122196**	**Micromed Morpheus, Brain Spy Plus K071782**
System Components	Ambulatory and Stationary Amplifiers, Adapter Cables, Signal Processor, Power Supply, (Interface to the user's Monitor and PC)	Ambulatory and Stationary Amplifiers, Adapter Cables, Signal Processor, Power Supply, (Interface to the user's Monitor and Personal Computer)	Ambulatory: Amplifier Basic: Amplifier, Adapter Cable, Signal Processor, Power Supply
Accessories	Ambulatory holster, data acquisition unit mounting pole, video camera mounting pole, equipment cart.	Ambulatory holster, data acquisition unit mounting pole, equipment cart.	None stated
Number of EEG Signal Recording Channels	System with SD LTM 64/32 EXPRESS: Up to 64 channels with one device. Up to 256 channels by cascading four devices System with MORPHEUS/ BRAIN SPY PLUS: 24	64 channels with one device. 128 channels by cascading two devices.	24 channels
Amplifier Input Impedance	System with SD LTM 64/32 EXPRESS: $>10^{12}$ Ω System with MORPHEUS/ BRAIN SPY PLUS: $>10^{9}$ Ω (diff)	$>10^{9}$ Ω (diff)	$>10^{9}$ Ω (diff)
Amplifier DC Signal Range	System with SD LTM 64/32 EXPRESS: 1.48 /4.8V (0.46/4.69 mV/digit) System with MORPHEUS/ BRAIN SPY PLUS: 1V	1V (15µV/digit)	1V (15µV/digit)
Amplifier Frequency	(15µV/digit) System with SD LTM 64/32 EXPRESS: 0.15-500 Hz	0.15 – 220 Hz	0.15 – 220 Hz

	Micromed BRAIN QUICK (Subject Device)	**Blackrock NeuroMed Cervello Basic Bio-Potential Signal Acquisition System K122196**	**Micromed Morpheus, Brain Spy Plus K071782**
Response	System with MORPHEUS/ BRAIN SPY PLUS: 0.15 – 220 Hz		
A/D Conversion	System with SD LTM 64/32 EXPRESS: 16 bit for EEG channels, 10 bit for DC channels System with MORPHEUS/ BRAIN SPY PLUS: 16 bit	16 bit	16 bit
Sampling Rate	8192 Hz per channel	8192 Hz per channel	8192 Hz per channel
CMRR	>100dB@50Hz between G1 and all other inputs	>100dB@20Hz between G1 and all other inputs	>100dB@20Hz between G1 and all other inputs
Noise	System with SD LTM 64/32 EXPRESS: <0.5µV r.m.s.@128Hz sampling rate System with MORPHEUS: <0.5µV r.m.s. @256Hz sampling rate	<0.5µV r.m.s.@128Hz sampling rate	<0.5µV r.m.s.@256Hz sampling rate
Power Source	Acquisition unit, 2x 1,5V DC AA, alkaline batteries, computer (for software), 120 VAC	Acquisition unit, 2x 1,5V DC AA, alkaline batteries, computer (for software), 120 VAC	2x 1,5V DC AA, alkaline batteries
Digital and Serial Input Channels	Yes	Yes	Yes
Measures	Impedance check Amplitude Frequency spectrum Time interval	Impedance check Amplitude Frequency spectrum Time interval	Impedance check
Extraction of Spike and Field Potentials	No	No	N/A
Alarms	No	No	No
Stimulation	None	None	None
Video camera	Available	Available	Available
Patient Contact	None - The device interfaces to user supplied bio-potential electrodes.	None - The device interfaces to user supplied bio-potential electrodes.	None - The device interfaces to user supplied bio-potential electrodes.
Operating System	Windows XP, 7, 8.1	Windows XP, 7, Server 2008 R2, Dual Core 2 GHz Processor	N/A
Device Input	Keyboard and Mouse	Keyboard and Mouse	N/A
Display	Computer Screen & Built-in LCD	Computer Screen	Built-in LCD

	Micromed BRAIN QUICK (Subject Device)	**Blackrock NeuroMed Cervello Basic Bio-Potential Signal Acquisition System K122196**	**Micromed Morpheus, Brain Spy Plus K071782**
Safety Standards Compliance	IEC 60601-1:2005 + /A1:2011 IEC 60601-1-2:2007 IEC 60601-2-26:2012	IEC 60601-1:1998 IEC 60601-1-2:2007 IEC 60601-2-26: 2002	IEC 60601-1 (1988)+ A1:1991 + A2:1995 (2nd edition) IEC 60601-1-1 2000-12 IEC 60601-1-2:2001-09 IEC 60601-1-4:1996 +A1:1999 IEC 60601-2-26:2002-11 UL 2601-1 ETSI EN 301 489-1 ETSI EN 301 489-17 ETSI EN 300 328-1

Discussion

Comparison with the predicate devices

The Micromed BRAIN QUICK system is a composition system based on devices already on the market in the U.S.A. The BRAIN QUICK system is comprised of one or more amplifiers, software and some accessories needed for supporting (PC, monitor, keyboard, separation transformer) or complementing (cart, video camera) the functions of the devices.

No patient contacting parts are included.

The integration of the amplifier, the software and the supporting accessories devices has already been performed in a similar system sold by Blackrock Neuromed, that is, the predicate device Cervello Basic system.

Similarities

- The amplifier used in the predicate system is identical to the SD LTM 64 EXPRESS amplifier used in the Micromed BRAIN QUICK system. It is a relabeling of the same device).
- The MORPHEUS amplifier used in the Micromed BRAIN QUICK system is identical to the amplifier submitted by Micromed under K071782.
- The software used in the Micromed BRAIN QUICK system provides the user with the same functionalities as the software included in the predicate Cervello Basic system.

Differences

- The Micromed BRAIN QUICK system differs from the Blackrock NeuroMed system in that the two systems use a different cart and a different isolation transformer.

- The software used in the Micromed BRAIN QUICK system is an updated version of the one used in the predicate system. The updates to the software version do not impact the safety or effectiveness of the subject device.

PERFORMANCE TESTING

Safety Tests have been performed to verify compliance with IEC 60601-1 and IEC 60601-2-26 to ensure that there are no potential hazards on patients, other persons, or the surroundings, and that basic safety and essential performance for EEG devices have been attained.

Electromagnetic Compatibility tests according to IEC 60601-1-2 have been performed to ensure no intolerable magnetic disturbances are introduced into its electromagnetic environment.

Immunity tests to IEC 60601-1-2 have been performed to ensure that the EEG equipment has the ability to operate satisfactorily in its electromagnetic environment

No specific guidance document on performance is required for EEG/PSG devices.

The device capability is equivalent to the features specified for predicate devices.

Verification of software was conducted according to Micromed design control procedures: it ensures that the system conforms to all the system design requirements

CONCLUSION

The Micromed BRAIN QUICK System has the same manner of use with basic functions as the predicate device and the Micromed BRAIN QUICK system has a similar requirement for training and expectations of user. The safety requirements and expectations are the same. The systems have comparable performance in terms of data sampling and accuracy. They use identical patient connectors and methodology.

Based on the information provided in this submission, we conclude that the Micromed BRAIN QUICK system is substantially equivalent to the predicate and is safe and effective for its intended use.