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K133419

JUL 2 1 2014

510(k) SUMMARY

This 510(k) Summary is being submitted pursuant to the requirements of 21 CFR 807.92(c).

1. Submitted By: Tristan Technologies, Inc.

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   Tristan Technologies, Inc.

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   Date prepared: July 17, 2014

2. Name of Device: Trade Name: Artemis 123 Biomagnetometer

   Common Name: Magnetic Encephalograph

   Regulation Name: Electroencephalograph (21 CFR 882.1400)

   Product Code: OLY

3. Predicate device:

The Artemis 123 Biomagnetometer is substantially equivalent to the Magnes 2500 WH Biomagnetometer System formerly manufactured and marketed by Biomagnetic Technologies, Inc., San Diego, CA. K962317

4. Description of Device:

The Tristan Technologies Artemis 123 Biomagnetometer (hereinafter referred to as the "Artemis 123") utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in brain. The Artemis 123 consists of a sensor unit, an electronics subsystem for preliminary amplification, filtering, and analog to digital conversion of the signals from each SQUID, an electronics rack containing power supplies to power the electronics subsystem, a computer to control the operation of the electronic subsystem and the SQUIDs and to acquire and store the signal values collected by the system, and a patient table which accommodates and facilitates the optimal positioning of the head of a human being adjacent to the sensor unit

5. Indications for Use:

The Tristan Technologies Artemis 123 Biomagnetometer is indicated for use for the patient whose physician believes that information about the magnetic fields produced by that patient's brain and information about the location of the sources of those magnetic fields could contribute to diagnosis or therapy planning.

6. Substantial Equivalence:

The Tristan Technologies Artemis 123 utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in brain. . The sensor comprises an array of 135 passive superconducting pickup coils, each of which is connected to a SQUID. The array is contained within an evacuated housing along with an insulated container for the cryogen liquid helium. The pickup coils and SQUIDs are refrigerated by solid thermal conduction to the cryogen. This is the identical technologies and methods of operation as used in the predicate device, the Magnes 2500 WH. The vacuum container is configured to have a helmet-like external shape at the top. This shape is sized and oriented to accommodate the positioning of the head of a human being lying in a supine position into the helmet-like shape. The pickup coils are positioned within the vacuum container to as to be in close proximity to the helmet-like shape, and thus when in use, to be in close proximity to the head of

the human being. This is also the identical method used in the Magnes 2500 WH although the latter was capable of being positioned to accommodate heads of human beings in the seated position as well as in a supine position.

For both the Artemis 123 and the Magnes 2500 WH, the output of each SQUID is a voltage the value of which is proportional to the magnetic field at the corresponding pickup coil. The voltage from each SQUID is amplified, filtered and digitized by signal processing electronics. The digitized signals are conveyed to a computer hard drive. The hard drive thus contains data comprising the voltage from each SQUID recorded as a function of time. This data is available to the user of the system for analysis and interpretation. The Artemis 123 as well as the Magnes 2500 WH may be operated by a physician, it may also be operated by a technologist working under the direction and supervision of a physician.

The following is a tabular comparison of the features and characteristics of the Magnes 2500 WH and the Artemis 123.

Element	Magnes 2500 WH	Artemis 123
Indications for use	Use of the Magnes 2500 WH is indicated for the patient whose physician believes that information about the magnetic fields produced by the patient's brain and information about the location of the sources of those magnetic fields could contribute to diagnosis or therapy planning.	Use of the Artemis 123 is indicated for the patient whose physician believes that information about the magnetic fields produced by the patient's brain and information about the location of the sources of those magnetic fields could contribute to diagnosis or therapy planning.
Underlying technology	Superconducting magnetometry	Superconducting magnetometry
Detector architecture	148 pickup coils arranged in helmet configuration	123 pickup coils arranged in helmet configuration
	13 offset pickup coils	12 offset pickup coils

	as reference channels	as reference channels
Pickup coil design	Two sets of magnetometer coils	One set of gradiometer coils
Average coil-to-coil spacing	25 mm	25 mm
Superconducting amplifiers	dc SQUID	dc SQUID
Refrigeration method	Solid conduction from liquid helium	Solid conduction from liquid helium
Data flow	SQUID output digitized, stored on hard drive	SQUID output digitized, stored on hard drive
Data acquisition	16 bits/channel 2 kHz sample rate	24 bits/channel 5 kHz sample rate
Host computer	Sun SPARCStation 20 Sun operating system	PC workstation MS Windows
Software	Proprietary data acquisition software; LabView® libraries	LabVIEW® based acquisition software
Sensitivity	10 femtoTesla/√ Hz average over channels	10 femtoTesla/√Hz average over channels
Patient interface	Provided patient table patient supine or seated	Provided patient table patient supine
Where used	Hospital or clinic	Hospital or clinic
Safety standard	IEC-60601-1	IEC 60601-1

7. Non-clinical test results

A prototype of the Artemis 123 was installed at the Children's Hospital of Philadelphia for research use only. Non-clinical tests of the device performance were conducted by hospital staff. These results were published in the peer-reviewed journal Frontiers of Human Neuroscience on 3 March 2014. Those results demonstrate the technological equivalence of the Artemis 123 to the Magnes 2500 with respect to sensitivity in a hospital environment and with respect to source localization in a phantom magnetic source.

To compare the sensitivity of the Artemis 123 in a hospital environment to that of the predicate device, the system was activated in the empty magnetically shielded room (MSR) and noise spectra of the output of all channels were recorded. The spectra of all channels were averaged together and that average spectrum is presented in the reference above. The average noise showed the same characteristic form as that of the Magnes 2500, with the noise level above 100 Hz being well below the specification of 10 fT/$\sqrt{}$Hz.

A second non-clinical test was conducted to record the magnetic field produced by a phantom containing two dipolar sources at known locations. The dipolar sources were each activated with a 40 Hz driving current, the magnetic field values recorded for each of the Artemis 123 channels, and those values fit to the model of a single dipole source. The results was a determination of the location of each dipole to within 5 mm of the actual location. This performance is also equivalent to the localization of dipoles in a phantom with the Magnes 2500 WH system.

8. Conclusions:

The Artemis 123 uses the identical underlying technology as the Magnes 2500 WH, employing superconducting pickup coils to measure and record the magnetic field at an array of locations around the surface of the head of a patient and placing the recorded values into a storage device for later review and examination by a user. The materials and methods used to construct the two systems are the same. The method of use of the two systems is the same. The indications for use of the Artemis 123 are the same as that of the Magnes 2500 WH. The primary difference between the two systems is the smaller physical size of the helmet of the Artemis 123 compared with that in Magnes 2500 WH. The sensitivity of the two systems in a noisy hospital environment is equivalent. The ability of each system to localize a dipolar source in a phantom is also equivalent. For these reasons, Tristan Technologies submits that the Artemis 123 is substantially equivalent to the Magnes 2500 WH.

Any questions regarding the 510(k) summary may be directed to the contact person noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 21, 2014

Tristan Technologies, Inc.
% Dr. Eugene C. Hirschkoff
3365 Calle Margarita
Encinitas, CA 92024

Re: K133419
Trade/Device Name: Artemis 123 Biomagnetometer
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLY
Dated: June 2, 2014
Received: June 17, 2014

Dear Dr. Hirschkoff:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133419

Device Name
Artemis 123 Biomagnetometer

Indications for Use *(Describe)*
Use of the Artemis 123 Biomagnetometer is indicated for the patient whose physician believes that information about the magnetic fields produced by that patient's brain and information about the location of the sources of those magnetic fields could contribute to diagnosis or therapy planning.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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