DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 8, 2016

Tristan Technologies, Inc
% Eugene Hirschkoff
Consultant
3365 Calle Margarita
Encinitas, California 92024

Re: K152184
Trade/Device Name: MagView Biomagnetometer
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLY
Dated: August 3, 2015
Received: August 5, 2015

Dear Eugene 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" (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.

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)*
K152184

Device Name
MagView Biomagnetometer

Indications for Use *(Describe)*
Use of the MagView 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. The intended patient populations are neonates and infants and those children with head circumferences of 50 cm or less.

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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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.

   6191 Cornerstone Ct., Ste 107

   San Diego, CA 92121

   (858) 550-2700

   Contact: Kevin Pratt, CEO

   Prepared: June 12, 2015

2. Name of Device: Trade Name: MagView Biomagnetometer

   Common Name: Magnetic Encephalograph

   Classification Name: 21CFR 882.1400 (Electroencephalograph)

   Product Code: OLY - Magnetoencephalograph

3. Substantial Equivalence:

   Conclusions drawn from the comparisons and testing summarized below demonstrate that the MagView Biomagnetometer is as safe, as effective, and performs as well as the Magnes 2500 WH Biomagnetometer System formerly manufactured and marketed by Biomagnetic Technologies, Inc., San Diego, CA, and is substantially equivalent to that predicate device.

4. Description of Device:

The Tristan Technologies MagView Biomagnetometer (hereinafter referred to as the "MagView") utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in brain. The MagView 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.

5. Intended Uses:

The Tristan Technologies MagView Biomagnetometer is intended 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. The intended patient populations are neonates and infants and those children with head circumferences of 50 cm or less.

6. Technological Characteristics:

The Tristan Technologies MagView utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in brain. This is the identical method of operation as that in the predicate Magnes 2500 WH. The MagView sensor comprises a primary array of 270 passive superconducting pickup coils, each of which is connected to a SQUID, a second array of 114 pickup coils spaced behind the primary array, each of which is also connected to a SQUID. By contrast, the predicate device employs 148 primary pickup coils and a second array of 8 pickup coils spaced behind the primary array. The pickup coils in the MagView are distributed over the same area of the head of a patient as are the coils in the predicate device. The sensitivity of each pickup coil is 10 femtoTesla/√ Hz in both the MagView and the Magnes 2500 WH,

over a bandwidth from 1 Hz to 1 kHz. In both systems, the second pickup coil array spaced behind the primary array is available for noise cancellation purposes.

In both systems, the pickup coil arrays are contained within an evacuated housing along with an insulated container for the cryogen liquid helium. The pickup coil arrays and SQUIDs are refrigerated by solid thermal conduction to the cryogen. For both the MagView and the predicate, the vacuum container is configured to have a helmet-like external shape at the bottom. 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 shape of the MagView "helmet" is smaller than that of the predicate device, and will be appropriate for patients with smaller head sizes. However, the sensitivity of each pickup coil is the same for both devices.

The primary array of pickup coils in the MagView is positioned within the vacuum container so 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.

In both the MagView and the predicate device, 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. In the MagView, the signal from each SQUID is digitized with 24 bit precision at a sample rate of 5 kHz; in the Magnes 2500, the signal from each SQUID is digitized with 16 bit precision at a sample rate of 2 kHz. The digitized signals are conveyed to a computer hard drive. In both systems, a 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. While the MagView may be operated by a physician, it may also be operated by a technologist working under the direction and supervision of a physician.

The MagView system has been tested and shown to comply with the following safety standards:

IEC 60601-1:1988 + A1:1991 + A2:1995

IEC 60601-1-2:2007 Third Edition

IEC 61000-4-2:2008

IEC 61000-4-3:2010

IEC 61000-4-4:2012

IEC 61000-4-5:2014

IEC 61000-4-6:2003

IEC 61000-4-11:2004

CISPR 11: 2010

In addition, non-clinical testing of the system was conducted on the MagView using external calibrated signal sources to demonstrate magnetic signal detection performance comparable to that of the predicate device. The sensitivity of the system, averaged over all primary channels, was measured to be 10 femtoTesla/√ Hz or better, over a bandwidth of 1Hz to 1 kHz, the same sensitivity and bandwidth offered by the Magnes 2500 WH.

7. Conclusions:

Measurement of magnetic fields originating from electrical activity in the brain has been undertaken for at least the past 30 years. The Magnes 2500 is a commercial device which performs these measurements and which has been legally marketed under a 510(k) procedure in 1996. See K962317. The Tristan Technologies MagView Biomagnetometer uses identical technology and methodology as used by the Magnes 2500, with a different number and geometric arrangement of the pickup coils and SQUIDs and with updated computer hardware and software. The intended use and indications for use are identical to that of the Magnes 2500.

Conclusions drawn from the non-clinical performance testing described above demonstrate that the MagView is as safe, as effective, and performs as well as the Magnes 2500 WH. Therefore, Tristan Technologies submits that the MagView is substantially equivalent to the Magnes 2500 WH

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