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

March 15, 2016

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

Re: K151135
Trade/Device Name: Model 621/624 Biomagnetometer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DPS
Dated: February 2, 2016
Received: February 9, 2016

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.

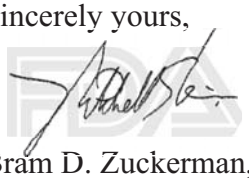
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*

K151135

Device Name

Tristan Technologies Model 621/624 Biomagnetometer

Indications for Use *(Describe)*

The Tristan Technologies Model 621/624 Biomagnetometer is intended for use as a tool that non-invasively measures and displays the magnetic signals produced by the electric currents in the heart of human beings of any age or in the heart of a fetus in utero.

Type of Use *(Select one or both, as applicable)*

X 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda. hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Tristan Technologies

6191 Cornerstone Court East, Suite 107
San Diego, CA 92121 USA
Phone: +1 (858) 550-2700
Fax: +1 (858) 550-2799
http://www.tristantech.com

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: April 17, 2015

2. Name of Device: Trade Name: Model 621/624 Biomagnetometer

   Common Name: Magnetocardiograph

   Classification Name: Magnetocardiograph

   Product Code: 74 DPS

3. Substantial Equivalence:

   The Model 621/624 Biomagnetometer is substantially equivalent to the CMI Magnetocardiograph, Model 2409 formerly manufactured and marketed by CardioMag Imaging, Inc., Schenectady, NY.

---

4. Description of Device:

The Tristan Technologies Model 621/624 Biomagnetometer (hereinafter referred to as the "Model 621/624") utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in the heart. The Model 621/624 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 Model 621/624 Biomagnetometer is intended for use as a tool that non-invasively measures and displays the magnetic signals produced by the electric currents in the heart of human beings of any age or in the heart of a fetus in utero.

6. Technological Characteristics:

The Tristan Technologies Model 621/624 Biomagnetometer utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in the heart. The sensor comprises an array of 21 passive superconducting pickup coils, each of which is connected to a SQUID. The array is immersed in a reservoir of the cryogen liquid helium contained within an insulated container called a dewar. The pickup coils and SQUIDs are refrigerated by direct contact with the liquid helium cryogen. This is the identical technology and method of operation as used in the predicate device, the Model 2409 CMI Magnetocardiograph produced and marketed by CardioMag Imaging, Inc. The dewar for the Model 621/624 is configured to have a flat bottom tail section with interior diameter selected to enable the 21 pickup coils to be distributed approximately uniformly over the interior bottom surface and with exterior diameter selected to permit placement over the chest of a human being. A standard option offered with the Model 621/624 is three additional superconducting pickup coils connected to three additional SQUIDs; these coils are located some distance away from the 21 primary pickup coils and provide reference signals which are available for user of the system to employ for purposes of signal processing.

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 Model 621/624 may be operated by a physician; it may also be operated by a technologist working under the direction and supervision of a physician.

7. Non-clinical test results

A prototype of the Model 621/624 was installed at the University of Wisconsin Department of Medical Physics for research use only. Non-clinical test measurements using the device were conducted by University staff. Those results were published in the peer-reviewed journal Physics in Medicine and Biology, **58,** (2013), pp. 8153-8161. (see Figures 3 and 4) Data for similar test measurements made using the CardioMag Model 2409 were published in the Annals of Non-invasive Electrocardiology, July 2005, vol. 10, pp. 312-323. (see Figure 4) Comparison of results demonstrate the technological equivalence of the Model 621/624 to the CardioMag Model 2409 for the measurement of magnetic signals produced by the human heart.

8. Conclusions:

Measurements of magnetic fields originating from electrical activity in the heart have been undertaken for at least the past 30 years. The Model 2409 CMI Magnetocardiograph produced and marketed by CardioMag Imaging, Inc. is a commercial device which performs these measurements and which is legally marketed under a 510(k) procedure completed in 2004. See K033488. The Tristan Technologies Model 621/624 Biomagnetometer uses identical technology and methodology as used by the CardioMag Model 2409 with an increased number of pickup antennae. Therefore, Tristan Technologies submits that its Model 621/624 Biomagnetometer is substantially equivalent to the CardioMag Model 2409.

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