March 15, 2019

Genetesis Inc.
Robert Sokolowski
VP Clinical, Quality and Regulatory
5412 Courseview Drive, Suite 150
Mason, Ohio 45040

Re: K182571
Trade/Device Name: CardioFlux *FAC* Magnetocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: February 8, 2019
Received: February 13, 2019

Dear Robert Sokolowski:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Arielle Drummond -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182571

Device Name

CardioFlux *FAC* Magnetocardiograph

Indications for Use *(Describe)*

The CardioFlux *FAC* Magnetocardiograph is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents of the heart.

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.

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

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GENETESIS INC.

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: September 10, 2018

SUBMITTER:

Genetesis Inc.
5412 Courseview Drive
Suite 150
Mason, OH 45040
Phone: 224-575-5577

PRIMARY CONTACT PERSON:

Robert Sokolowski, PhD
VP Clinical, Quality and Regulatory
Genetesis Inc.
Suite 150
Mason, OH 45040
Phone: 224-575-5577

DEVICE:

TRADE NAME: CardioFlux *FAC* Magnetocardiograph
COMMON NAME: Magnetocardiograph
DEVICE CLASS: Class II
CLASSIFICATION NAME: Electrocardiograph (21 CFR 870.2340)
PRODUCT CODE: DPS

PREDICATE DEVICE(S):

K151135 Tristan Technologies Model 621/624 Biomagnetometer

DEVICE DESCRIPTION:

The CardioFlux *FAC* Magnetocardiograph (MCG) is a biomagnetic sensing device that can record and display the magnetic fields generated by cardiac electrical activity. The CardioFlux *FAC* hardware connects to the Faraday™ Analytical Cloud (*FAC*) to allow access to a patient database and software for data analysis. The CardioFlux *FAC* MCG system consists of a patient table, a 6 x 6 array of optically pumped magnetometers covering roughly an area of 400 square centimeters and a shielding cylinder to reduce ambient electromagnetic interference during a patient scan. CardioFlux *FAC* is primarily controlled via software applications on a local computer. Data are displayed as 36 superimposed cardiocycles and magnetic field maps.

GENETESIS INC.

INDICATIONS FOR USE:

The CardioFlux *FAC* Magnetocardiograph is intended for use as a tool which non-invasively measures and displays the magnetic signals produced by the electric currents of the heart.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use of Genetesis' CardioFlux *FAC* MCG system are the same as those of the predicate devices without the additional statement that it is intended for fetal measurements.

Technological Comparison
The table below identifies technological similarities and differences between the proposed CardioFlux *FAC* MCG system and the Tristan 621/624 Biomagnetometer (K151135).

	CardioFlux FAC MCG (Proposed Device)	***Model 621/624 Biomagnetometer (Predicate Device)***	***Similar***	***Different***
Installation	Fixed	Fixed	X	
Power Source	100 – 120 V, 60 Hz	110, 60 Hz	X	
Electromagnetic shielding	Multilayer open-ended cylindrical shielding chamber surrounding patient and sensor head	Multilayer closed shielding room surrounding patient and sensor head	X	
Sensor Array - Patient Positioning	Manual positioning of sensor array; motor-driven bed.	Manual positioning of sensor array; motor-driven bed.	X	
Magnetic Field Detection	Magnetometer	Gradiometer		X
Number of z-axis Sensors	36	7		X
Sensor Thermal Control Requirement	Yes	Yes	X	
Operating System	Windows	Windows	X	
Platform	Dedicated computer for data acquisition and Cloud-based data storage and processing	Dedicated computer		X
Patient database	Yes	Yes	X	
Data acquisition	1000 Hz	1000 Hz	X	
Filtering	Digital	Digital	X	
Magnetic field tracing	Available for each sensor	Available for each sensor	X	

Summary of Non-clinical Tests

The CardioFlux *FAC* Magnetocardiograph complies with voluntary standards for electrical safety and electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

- Risk analysis developed in accordance with ISO 14971:2007
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012 standard and IEC 60601-1-2: 2014 standards, respectively.
- Performance Testing (head-to-head against the predicate device) to determine the ability of CardioFlux *FAC* to record human cardiac biomagnetic signals from male and female adults ranging in age from 23 to 77. Analysis of the magnetic field traces of each volunteer showed excellent qualitative and quantitative agreement between data acquired with the proposed device and data acquired with the predicate.

CONCLUSION:

The differences between the Genetesis CardioFlux *FAC* MCG system and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

In conclusion, from the results of nonclinical testing described, the CardioFlux *FAC* MCG system is substantially equivalent to the legally marketed predicate device.