DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 19, 2014

CardioInsight Technologies, Inc.
Ms. Christina V. Vacca
Vice President Quality, Regulatory Affairs and Operations
11000 Cedar Ave., Suite 210
Cleveland, OH 44106

Re: K140497
Trade/Device Names: CardioInsight ECVUE Mapping System
Regulatory Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (Two)
Product Code: DQK
Dated: October 21, 2014
Received: October 22, 2014

Dear Ms. Vacca:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Melissa A. Torres -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
ECVUE

Indications for Use *(Describe)*

The CardioInsight ECVUE Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

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)*

Submitter:	CardioInsight Technologies, Inc. 11000 Cedar Ave, Suite 210 Cleveland, OH 44106 chris@cardioinsight.com Office: 216-453-5950 ext 105 Mobile: 440-315-6973
Contact Person:	Christina V. Vacca Vice President Quality, Regulatory Affairs and Operations
Date Prepared:	October 21, 2014
Name and Classification	ECVUE™ Electrophysiological cardiac mapping system: 21 CFR Programmable diagnostic computer 870.1425, DQK
Predicate Device(s):	The legally marketed device to which we are claiming equivalence is Bard LabSystem PRO EP Recording System (K113811)
Summary	ECVUE is a non-invasive mapping system for beat-by-beat, multi-chamber, 3D mapping of the heart. The system displays cardiac maps and virtual electrograms from real-time chest ECG signals (measured by a Sensor Array placed on the torso) and CT scan data. The ECVUE software provides various cardiac signal analyses and displays interactive 3D color maps including potential, activation, voltage, propagation, and phase maps. The system is mobile and can be used for mapping at the patient's bedside or in the EP lab.
Intended/Indication for Use:	The CardioInsight ECVUE Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.
Device Characteristics Compared to the Predicate	<u>Performance Testing: Bench</u> To assure reliable design and performance, the Company performed in vitro testing including software and hardware verification and validation, electrical safety testing, and electromagnetic compatibility testing. The test results demonstrate that the ECVUE mapping system meets the applicable standards and specifications. <u>Performance Testing: Animal</u> A GLP study was conducted to demonstrate the performance of the ECVUE system in identifying origin and pattern of various rhythms as compared to a standard electrophysiology (EP) study in a controlled porcine model. The ability of the ECVUE system to acquire ECG signals, perform signal analyses, and display 3D maps to localize various rhythms and characterize cycle length and

activation times was established in this study. There were no adverse events. The study clearly demonstrated the substantial equivalence of the ECVUE system to the legally marketed predicate devices.

Performance Testing: Clinical Experience with commercially available device

Clinical experience from 60 patients, representing the use of the ECVUE system in routine EP clinical practice from two European centers were included to complement the results of the GLP animal study. There have been no adverse events reported with the use of ECVUE. These clinical data provide strong supporting information indicating that in routine EP clinical practice, the non-invasive ECVUE system is safe and performs as intended.

Conclusion:

CardioInsight believes the ECVUE mapping system is substantially equivalent to the predicate devices.

The conclusions drawn from in-vitro testing, GLP animal testing and clinical experience (discussed above) demonstrate that the device is equivalent and is as safe and effective as the predicate devices.