



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

July 2, 2015

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

Re: K150990

Trade/Device Name: ECVUE Mapping System, Model AT200  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: Class II (two)  
Product Code: DQK  
Dated: June 9, 2015  
Received: June 12, 2015

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 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150990

Device Name

ECVUE Mapping System

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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**K150990 510(k) Summary**

<b>Submitter</b>	CardioInsight Technologies, Inc. 11000 Cedar Ave, Suite 210 Cleveland, OH 44106
<b>Contact Person</b>	Christina V. Vacca Vice President Quality, Regulatory Affairs and Operations CardioInsight Technologies, Inc. 11000 Cedar Ave, Suite 210 Cleveland, OH 44106 chris@cardioinsight.com Office: 216-453-5950 ext. 105 Mobile: 440-315-6973
<b>Date Prepared</b>	June 9, 2015
<b>Trade Name</b>	ECVUE™ Mapping System
<b>Classification</b>	21 CFR 870.1425, Electrophysiological cardiac mapping system: Programmable diagnostic computer, Class II
<b>Product Code</b>	DQK
<b>Predicate Device</b>	ECVUE Mapping System (K140497)
<b>Device Description</b>	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.
<b>Intended Use</b>	The CardioInsight ECVUE Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.
<b>Comparison of Technological Characteristics</b>	<p>The modified ECVUE Mapping System is as follows:</p> <ul style="list-style-type: none"> <li>• Similarities to the unmodified device: <ul style="list-style-type: none"> <li>• Identical intended use/indications for use</li> <li>• Identical operating principle</li> <li>• Incorporate same basic design</li> <li>• Same hardware components</li> <li>• Identical fundamental technology</li> <li>• Identical manufacturing and quality control procedures</li> </ul> </li> <li>• Differences compared to unmodified device: The original ECVUE Mapping System has been modified by updates to the software based on internal/user feedback and maintenance updates to the OTS. These changes to the software are very small and do not change the functionality or technological characteristics of the device. The Intended Use of the device is not affected. Testing demonstrated that the modified ECVUE Mapping</li> </ul>

	System is substantially equivalent to the original (predicate) system.
<b>Non-Clinical Testing</b>	Full system, integration, unit regression testing was performed.
<b>Clinical Testing</b>	No clinical testing was conducted.
<b>Conclusion</b>	Testing showed that the modified ECVUE Mapping System is substantially equivalent to the original (predicate) system and the changes did not affect the safety and effectiveness of the device when it is used as labeled