K120282

DEC 10 2012

Paieon
Realizing Cardiac Imaging

510(k) SUMMARY- CardNav

Submitter Name:	Paieon Inc.
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Date Prepared:	October 31, 2012
Device Trade Name:	CardNav
Device Common Name:	Cardiovascular Angiography Analysis System
Classification Name:	Image-intensified fluoroscopic x-ray system (product code OWB)
Predicate Devices:	1. The IC-PRO System (version 3.5, model B) cleared under K110256; 2. The 4D LV-Analysis software cleared under K110746; 3. The syngo Vector Velocity Imaging application cleared with the Diagnostic Ultrasound System with Accessories under K072090; 4. The Cardiac Motion Quantification Plugin (CMQ) which is a part of the QLAB software included with the Q-Station cleared under K103815.
Device Description:	CardNav (version 1.0) is an image acquisition and processing modular software package designed as an add-on to conventional X-ray angiography systems. It enhances the output of cardiovascular angiography by providing software modules that assist in diagnosis, procedure planning and therapeutic staging. This data is obtained without altering the basic angiography procedure. The CardNav software is to be used with patients undergoing device placement in the coronary venous system.

Intended Use:	**CardNav,** an image acquisition and processing modular software package, is indicated for use as follows: ▪ Assist in projection selection using 3D modeling based on 2D images. ▪ Perform quantitative analysis on coronary veins based on fluoroscopy images. ▪ Assists in device positioning by providing real time localization on predefined roadmaps and live fluoroscopy. ▪ Perform motion analysis on coronary veins based on fluoroscopy images. ▪ To be used in cardiac procedures and off-line for post-procedural analysis.
Performance Standards:	None
Performance Data:	Testing included in-house software verification testing, on-site system evaluation, bench testing using phantoms and retrospective clinical data, and animal study comparing device results with a sonomicrometry measurement method. The results of the testing indicate that CardNav 1.0 performs as intended and is safe for its intended use.
Substantial Equivalence:	The intended uses of CardNav (version 1.0) are substantially equivalent to a combination of the intended use of the predicate devises. All CardNav 1.0 technological characteristics, except motion analysis are the same as the cleared IC-PRO (version 3.5, model B) system; the motion analysis is technologically different from the predicate devices in terms of imaging modality and different output, but similar in terms of temporal resolution. Performance data was provided and showed that the device is safe and effective.
Conclusion:	The testing reported in this 510(K) establishes that the CardNav (version 1.0) is substantially equivalent to its predicate device and it is safe and effective for its intended use.

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

December 10, 2012

Paion, Inc.
% Mr. Shimon Vaknin
Official Correspondent
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ISRAEL

Re: K120282
Trade/Device Name: CardNav
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB AND LLZ
Dated: November 30, 2012
Received: December 3, 2012

Dear Mr. Vaknin:

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,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120282

Device Name: CardNav 1.0

Indications For Use:

CardNav, an image acquisition and processing modular software package, is indicated for use as follows:

- Assist in projection selection using 3D modeling based on 2D images.
- Perform quantitative analysis on coronary veins based on fluoroscopy images.
- Assists in device positioning by providing real time localization on predefined roadmaps and live fluoroscopy.
- Perform motion analysis on coronary veins based on fluoroscopy images.
- To be used in cardiac procedures and off-line for post-procedural analysis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
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