K113594

Paieon
Realizing Cardiac Imaging

510(k) SUMMARY- C-THV System

MAR - 2 2012

Submitter Name:	Paieon Inc.
Submitter Address:	747 Third Ave., 4th floor New York, NY 10017-2803
Contact Person:	Erez Ben-Zvi
Phone Number:	+972 3 915 0000
Fax Number:	+972 3 901 2324
Date Prepared:	November 24, 2011
Device Trade Name:	C-THV System
Device Common Name:	Cardiovascular Angiography Analysis System
Classification Name:	Angiographic x-ray system
Predicate Devices:	The IC-PRO System (version 3.5, model B) cleared under K110256;
Device Description:	The C-THV (version 4.6) system is an image acquisition and processing modular software package designed as an add-on to conventional X-ray angiography systems. This system enhances the output of cardiovascular angiography by providing software modules that assist in diagnosis, procedure planning, therapeutic staging and post deployment analysis. The C-THV provides quantitative data of vessel and localizes device on predefined roadmaps. The C-THV is intended to be used in patients with vascular, congenital, valvular, and myopathic heart disease as well as with patients undergoing artificial valve deployment. The C-THV package includes and elaborates on previously developed, 510(k) cleared, and marketed modules of IC-PRO (version 3.5, model B) system. It comprised of the following modules: a. Optimal Projection b. Dimensional Measurements c. Virtual Valve d. Positioning

Intended Use:	**C-THV**, an image acquisition and processing modular software package, is indicated for use as follows: ▪ Assists in projection selection using 3D modeling based on 2D images ▪ Performs dimensional measurements based on DICOM images. ▪ Assists in device positioning by providing real time localization on predefined roadmaps and live fluoroscopy. The system is to be used in-procedure and off-line for post-procedural analysis.
Performance Standards:	None
Performance Data:	Testing included software validation and performance evaluation. Performance tests have yielded accuracy and precision results within the predetermined specifications.
Substantial Equivalence:	All C-THV System modules are substantially equivalent to their cleared predicate device modules in terms of indication and intended use, technological characteristics, input and output, measurements and operating environment. All C-THV System modules, but the positioning are functioned the same, have similar specifications and performances as in IC-PRO System (version 3.5, model B). The IC-PRO System is also an image acquisition and processing software that has the ability to work with DICOM XA and Bitmap imaging formats. All found differences raise no new safety and effectiveness issues or concerns.
Conclusion:	The testing reported in this 510(K) establishes that the C-THV (version 4.6) 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 Room – WO66-G609
Silver Spring, MD 20993-0002

Paieon Medical Ltd.
% Mr. Omer Barlev
CEO
Paieon, Inc.
747 Third Ave., 4th Floor
NEW YORK NY 10017-2803

MAR - 2 2012

Re: K113594
Trade/Device Name: The C-THV System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI and LLZ
Dated: November 24, 2011
Received: December 5, 2011

Dear Mr. Barlev:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: **The C-THV System**

Indications for Use:

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

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- Assists in projection selection using 3D modeling based on 2D images
- Performs dimensional measurements based on DICOM images.
- Assists in device positioning by providing real time localization on predefined roadmaps and live fluoroscopy.

The system is to be used in-procedure and off-line for post-procedural analysis.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Posted November 13, 2003)

Mary S Pastel
Division Sign-Off
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113594