K113063

NOV 10 2011

510(k) SUMMARY

ActiViews's CT-Guide Needle Guidance System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: October 14, 2011

Name of Device and Name/Address of Sponsor

CT-Guide Needle Guidance System
ActiViews Ltd
7 Nahum Haat St.
Haifa 31905
Israel

Common or Usual Name/ Classification Name

Computed Tomography X-ray System Accessory

Predicate Device

ActiViews Ltd.'s CT-Guide Needle Guidance System (K110812)

Intended Use/Indications for Use

The CT-Guide is a stereotactic accessory for Computed Tomography ("CT") systems. The CT-Guide displays an interventional instrument on a computer monitor that also displays a CT-based model of the target organ(s).

The CT-Guide is intended to be used in clinical interventions in the lung, where CT is currently used for visualizing such procedures.

Technological Characteristics

The CT-Guide System is comprised of four main components: (1) the ActiSensor, a disposable video camera that is mounted onto a holder, which is clipped to a needle; (2) the ActiSticker, a disposable pad, which provides visual and radio-opaque reference markers; (3) a workstation that contains a dedicated computer; and (4) accompanying computer software.

Purpose of the Special 510(k) Notice

The purpose of this Special 510(k) notice is to address hardware and software design modifications to the cleared CT-Guide Needle Guidance System cleared via K110812. The device modifications include:

- Modification of the ActiSticker design to include 3 entry holes instead of 1 entry hole in the previous version of the system, as well as to the system software to support this change in the ActiSticker.
- Various software modifications implemented to provide improved user interface and additional information to the user during the procedure.
- System level changes that include the following: new version of the computer, the cart, the monitor and a change in the operating system. The computer, cart and the monitor have been updated to a newer version and meet or exceed the predefined specifications in the originally cleared version of the device.

Performance Data

The modified CT-Guide Needle Guidance System was tested for its performance and accuracy through several bench tests conducted on a custom phantom setup. All results were satisfactory and met the predefined specifications. The CT-Guide modified software was validated and tested. In addition, the CT-Guide system was retested for electromagnetic compatibility and electrical safety per IEC 60601-1 and IEC 60601-1-2. In all instances, the CT-Guide functioned as intended and the testing results observed were as expected.

Substantial Equivalence

The modified CT-Guide Needle Guidance System has the same intended use and indications, and similar principles of operation, and technological characteristics as the previously cleared CT-Guide Needle Guidance System. The minor differences in the modified CT-Guide Needle Guidance System's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified CT-Guide Needle Guidance System is as safe and effective as the predicate CT-Guide Needle Guidance System. Thus, the modified CT-Guide Needle Guidance System is substantially equivalent to its identified predicate device.

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

NOV 10 2011

ActiViews, Ltd.
% John J. Smith , M.D., J.D.
Regulatory Counsel
Hogans Lovells, US LLP
555 13th Street, NW
WASHINGTON DC 20004

Re: K113063
Trade/Device Name: CT-Guide Needle Guidance System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 14, 2011
Received: October 14, 2011

Dear Dr. Smith:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CT-Guide Needle Guidance System

Indications for Use:

The CT-Guide is a stereotactic accessory for Computed Tomography ("CT") systems. The CT-Guide displays an interventional instrument on a computer monitor that also displays a CT-based model of the target organ(s).

The CT-Guide is intended to be used in clinical interventions in the lung, where CT is currently used for visualizing such procedures.

Prescription Use ___X___ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K 113063