



Food and Drug Administration  
10903 New Hampshire Avenue  
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KEOSYS SAS  
% Ms. Laurence Boy-Machefer  
Regulatory Affairs and Quality Assurance Manager  
13 Impasse Serge Reggiani, B.P. 10222  
Saint Herblain cedex, 44815  
FRANCE

June 21, 2016

Re: K160334  
Trade/Device Name: Advanced Medical Imaging Software Suite (KSWVWR)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: May 13, 2016  
Received: May 16, 2016

Dear Ms. Boy-Machefer:

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” (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 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 that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the typed name.

Robert Ochs, Ph.D.  
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)  
K160334

Device Name  
Advanced Medical Imaging Software Suite (KSWVWR)

### Indications for Use (Describe)

Keosys Medical Imaging Suite (KSWVWR) is intended to be used by trained medical professionals included, but not limited to, radiologists, nuclear medicine physicians and physicists.

Keosys Medical Imaging Suite is a software application intended to aid in diagnostic and evaluation of medical image data. Although this device allows the visualization of mammography images, it is not intended as a tool for primary diagnosis in mammography.

Keosys Medical Imaging Suite can be used for display, process, temporarily store, print and also create and print reports from 2D and 3D multimodal DICOM medical image data. The imaging data can be Computed Tomography (CT), Magnetic Resonance (MR), Radiography X (CR, DX, XA, XRF, MG), Nuclear Medicine (NM) including planar imaging (Static, Whole body, Dynamic, Gated) and tomographic imaging (SPECT, Gated SPECT), Positron Emission Tomography (PET), Ultrasound (US).

Keosys Medical Imaging suite provides tools like rulers, markers or region of interests (e.g. it can be used in an oncology clinical workflow for tumor burden assessment or therapeutic response evaluation).

It is the user responsibility to check that the ambient luminosity conditions, the images compression ratio and the interpretation monitor specifications are consistent with a clinical diagnostic use of the data.

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.

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## 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for KSWVWR in conformance with 21 CFR 807.92.

**Date Prepared:** January 2016.  
**Submitter:** Keosys S.A.S.  
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**Contact Telephone:** 00 33 (0)2 53 59 12 90  
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**Device Trade Name:** Advanced Medical Imaging Software Suite (KSWVWR)  
**Device Common Name:** Viewer  
**Device Classification Name:** Picture Archiving and Communication System  
**Classification Panel:** 21 CFR §892.2050  
**Product code:** LLZ  
**Device Classification:** Class II  
**Predicate Devices:**

Name	Manufacturer	510(k) number
Myrian	Intrasense	K113620
MIM 5.2	MIM Software	K103576
XD	Mirada	K101228
Hermes Medical Imaging Software Suite v5.4	Hermes Medical Solutions AB	K140269
Imagys	Keosys S.A.S	K102000

### I) Device Description:

Keosys' Advanced Medical Imaging Software Suite (aka Viewer, aka KSWVWR) is a multimodality diagnostic workstation for visualization and 3D post-processing of Radiological and Nuclear Medicine medical images. It includes dedicated applications for the therapeutic response evaluation process in a multi-vendor, multi-modal and multi time-points context. The solution also includes the latest recommendations for SUV calculation.

### II) Indications for Use:

Keosys Medical Imaging Suite (KSWVWR) is intended to be used by trained medical professionals included, but not limited to, radiologists, nuclear medicine physicians and physicists.

Keosys Medical Imaging Suite is a software application intended to aid in diagnostic and evaluation of medical image data. Although this device allows the visualization of mammography images, it is not intended as a tool for primary diagnosis in mammography.

Keosys Medical Imaging Suite can be used for display, process, temporarily store, print and also create and print reports from 2D and 3D multimodal DICOM medical image data. The imaging data can be Computed Tomography (CT), Magnetic Resonance (MR), Radiography X (CR, DX, XA, XRF, MG), Nuclear Medicine (NM) including planar imaging (Static, Whole body, Dynamic, Gated) and tomographic imaging (SPECT, Gated SPECT), Positron Emission Tomography (PET), Ultrasound (US).

Keosys Medical Imaging suite provides tools like rulers, markers or region of interests (e.g. it can be used in an oncology clinical workflow for tumor burden assessment or therapeutic response evaluation).

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### **III) Comparison of the technical characteristics between the device and its predicate devices:**

The intended use of the Viewer and the Substantial Equivalent devices are similar with regard to the following points:

- all of the devices are providing tools to aid the physician in the diagnosis of patient,
- all of the devices support display, manipulation and fuse tools,
- all of the devices can use medical images from multiple modalities as SPECT, PET, CT, etc.

The indications for use of the Viewer and SE devices are similar for the reasons expressed in the above point.

The target population is globally the same for all the devices.

All of the devices can be used inside and outside the medical environment (within the “intended use” and the “indications for use” limits). Systems requirements differs only slightly.

The devices are not using any energy apart from the electrical needs for the computer power supply. Moreover, there’s no energy delivered.

The Viewer and SE devices are all software components which rely on some human factors represented by the user of the device.

The general design of all the devices software appears to be identical, based on available data.

All of the devices have specific manufacturer’s software methods and software test procedures to address the performance and functional testing.

### **IV) Testing:**

Keosys Medical Imaging Advanced Software Suite is tested according to the specifications that are documented in a Software Test Plan. Performance and functional testing are an integral part of Keosys’s software development process.