



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 13, 2014

Dalian Senyint Digital Medical System Co., Ltd.
% Mr. Leon Lu
Director of Quality and Regulatory Affairs
3500 South Dupont Highway
DOVER DE 19901

Re: K133098
Trade/Device Name: Senyint PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 1, 2014
Received: June 9, 2014

Dear Mr. Lu:

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,



for

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)

K133098

Device Name

Senyint PACS

Indications for Use (Describe)

Senyint PACS is a Picture Archiving and Communication (PACS) software system.

It is a software system including several applications working together whose intended use is to provide completely scalable local and wide area PACS solutions for hospital, related Institutions and sites.

Senyint PACS provides several server applications that receive images from medical imaging modalities (including but not limited to CT, MRI, CR, OR, MG, US, RF, PET and other DICOM devices), store and archive them, and distribute them to DICOM devices, 3rd party Image View Workstation, Senyint PACS Web-Viewer, etc.

Senyint PACS provides a Client Image View Workstation. It allows the user to access patient records and retrieve images from the PACS server in a network. Senyint Image View Workstation has a simple GUI for viewing images in 2D and 3D mode. The functions in 2D mode including zoom, pan, windowing, basic measurements, image mosaic, cine, etc. It also display images from CT, MR and PET in the 3D mode including MPR, OPR, CPR, VR, VE, MIP, MiniIP, AIP, tissue segmentation, Batch reconstruction, etc. In addition, using this Workstation, users can edit report and print film.

Senyint PACS provides a Web-Viewer that is a browser-based web application. It allows the user to access patient records and retrieve images from the Senyint PACS server in a wide area setup. The Web-Viewer has a simple GUI for viewing images including zoom, pan, windowing, basic measurements, cine, etc. It provides a diagnostic viewer of medical images for referral purposes. It is not intended to replace full workstations and should be used only when there is no access to a workstation. It is available as a supplement sub-system to Senyint PACS or as a stand-alone Web-based image and information distribution system. It is not intended to be used on mobile device platforms(e.g., iPad, iPhone).

Senyint PACS Manager Workstation is used to set the basic information on the management of the system so that the system can work normally. Only authorized users to be able to visit our workstations to operate.

Typical users of Senyint PACS are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

