K092235

AUG 0 6 2009

Attachment 1

Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Trade Name:	BeyondImage Workstation
Version Number:	1.0
Common Name:	Picture Archiving and Communication System (PACS)
CFR Section:	21 CFR Part 892.2050
Classification Name:	Picture Archiving and Communication System (PACS).
Product Code:	LLZ
Device Class:	Class II
Applicable Standard:	NEMA PS 3.1 - 3.18 (2004), Digital Imaging and Communications in Medicine (DICOM)
Manufacturer and Distributor:	Neusoft Medical Systems Co., Ltd. No.16,Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China Post Code : 110179
Submitter:	Contact : Tian Yuehui Title : Manager of Quality Management Department Tel : 86-24-83660646 Fax : 86-24-83660563 E-Mail : Tianyh@neusoft.com
	Summary prepared : July. 30, 2009

Safety and Effectiveness Information

Intended Uses:

BeyondImage Workstation is a software application that is used for viewing medical images. BeyondImage Workstation receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and digital radiographic devices). Images are stored, communicated, processed and displayed on the local disc of a workstation and/or across computer networks at distributed locations. Tasks that users may perform when viewing images include, but are not limited to adjustment of window width and center; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images. It also provides standard Multi-Planar Reformation (MPR) views and 3D views of Volume Rendering for digital images from CT, MR, and PET unit. In addition, using BeyondImage Workstation, users can edit and print report. BeyondImage Workstation cannot display and process mammograms.

Typical users of BeyondImage Workstation are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Device Description:

BeyondImage Workstation is a software application that provides image viewing and manipulation in a diagnostic imaging setting. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM format. BeyondImage Workstation can also transfer images in DICOM 3.0 format over a medical imaging network, as well as exporting images to applications in other proprietary formats.

BeyondImage Workstation cannot receive, display and process the images with non-DICOM3.0 format.

BeyondImage Workstation cannot display and process mammograms.

Predicate Device:

K012211 : eFilm Workstation
K073062 : Omni-Vue System

Statement of Substantial Equivalence:

The BeyondImage Workstation is comparable and substantially equivalent to the eFilm Workstation (K012211) and the Omni-Vue System (K073062).

BeyondImage Workstation, eFilm Workstation and Omni-Vue System are all available as "software only" application that run under Microsoft Windows operating systems on readily available computer hardware. All applications include image and report viewing and a set of imaging measurements and manipulation tools. All three are DICOM compliant systems capable of receiving and storing images and moving imaging studies using DICOM Query/Retrieve.

The BeyondImage Workstation and the eFilm Workstation share similar technological specifications. Both of them support DICOM protocol for communication of images with other medical imaging devices, and they both provide the functions such as adjustment of window width and center; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images etc. Furthermore, they both provide standard Multi-Planar Reformation (MPR) views and 3D views of Volume Rendering.

The BeyondImage Workstation has the similar technological characteristics with the Omni-Vue System. Both of them support DICOM protocol for communication of images with other medical imaging devices, and they both provide the functions such as adjustment of window width and center, scout line, annotation and measurement of regions of interest; and inversion, rotation, and flips of images etc. Furthermore, they both provide functions to edit and print report.

According to the comparison based on the requirements of 21.CFR 807.87, we state that these devices are substantially equivalent.

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

Neusoft Medical Systems Co., Ltd.
% Mr. Tamas Borsai
Division Manager
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

AUG 0 6 2009

Re: K092235
Trade/Device Name: BeyondImage Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 21, 2009
Received: July 23, 2009

Dear Mr. Borsai:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number: K092235

Device Name: BeyondImage Workstation

BeyondImage Workstation is a software application that is used for viewing medical images. BeyondImage Workstation receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and digital radiographic devices). Images are stored, communicated, processed and displayed on the local disc of a workstation and/or across computer networks at distributed locations. Tasks that users may perform when viewing images include, but are not limited to adjustment of window width and center; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images. It also provides standard Multi-Planar Reformation (MPR) views and 3D views of Volume Rendering for digital images from CT, MR, and PET unit. In addition, using BeyondImage Workstation, users can edit and print report. BeyondImage Workstation cannot display and process mammograms.

Typical users of BeyondImage Workstation are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Prescription Use YES (Part 21 CFR 801 Subpart D)

Over-The-Counter Use NO (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092235