K070755

MAY 8 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (21CFR 807.92)

I. DATE PREPARED: 03/09/2007

II. SUBMITTER:

Avreo, Inc.
336 Camp Street
New Orleans, LA 70130

III. CONTACT PERSON:

Nancy Butcher
VP of Quality Assurance
Avreo, Inc.
(214)-244-1798

IV. DEVICE NAME:

Classification Name: Picture Archiving and Communications System (PACS)
Trade/Proprietary Name: InterWorks™

V. DEVICE CLASSIFICATION

Class II
CFR section: 892.2050
Product code: LLZ
Panel: Radiology

VI. PREDICATE DEVICES:

K043146
Horizon Medical Imaging (McKesson Medical Imaging Company)
Class II
Decision Date: 1/04/05

K042832
Sienet Cosmos (Siemens Medical Solutions)
Class II
Decision Date: 10/28/04

VII. SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

Avreo, Inc. concludes that the intended use for the Avreo InterWorks™ System is the same as that of the predicate devices, and that the technological characteristics demonstrate that they are equivalent to the predicate device. A comparison of the technological characteristics of the predicate and legally marketed devices available has been performed.
Thus, this premarket notification has demonstrated substantial equivalence.

VIII. DEVICE DESCRIPTION AND INTENDED USE:

InterWorks™ is comprised of software modules that can work together to deliver an integrated solution that provides image capture, storage, distribution, enhancement, manipulation, and networking of medical images at distributed locations.

The Image Management module that manages your imaging needs for a Radiology Enterprise. All of the different facets are unified under a single system that acquires, distributes, storages, displays and prints medical images. By interVIEW supporting DICOM 3.0 it can Plug-n-Play with other DICOM 3.0 compliant devices with minimal effort. For Practices that are in need of only Tele-Radiology functionality interVIEW TR will meet all the needs.

The Dictation/Transcription module that provides for reliable creation of Radiology reports for your Radiology Enterprise. Reports are created via Voice Recognition with interSCRIBE VR or Digital Dictation with interSCRIBE DD depending upon the individual preferences of the Radiologist and requirements of the Radiology Enterprise. In either case digital files are created by the Radiologist and sent to transcription worklists for transcribing or editing by transcriptionists using interSCRIBE DT. Once the report has been finalized it is electronically signed by the Radiologist and automatically delivered via fax and/or e-mail to referring physicians.

The Radiology Information System module manages your radiology workflow for your Front Desk, Back Office and Clinical operations. All of the different areas of operations are unified under a single system that extends beyond the physical walls to exchange information and perform transactions with important business partners. Most importantly, the rules engine that drives interFLOW can be tailored.

Intended Use

InterWorks™ product is intended to provide a completely scalable PACS solution for hospitals and other related sites, which will distribute, retrieve archive, and display, data and images from a variety of different modality and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation", and will include standard features and other Mammo tools. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Application areas include imaging centers, radiologist central reading rooms and any other locations where trained medical professionals would require access or desire patient images, demographic information or other patient medical information captured in the system.

IX. SAFETY INFORMATION:

The Avreo InterWorks™ System has no patient contact and is utilized only by trained professionals. Trained professionals allow sufficient review to afford identification and intervention in the event of a malfunction have evaluated the output of the device.

X. CONCLUSION:

Avreo, Inc. believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the subject device is as safe and effective including the component and accessory devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 8 2007

Ms. Nancy Butcher
Vice President of Quality Assurance
Avreo, Inc.
Corporate Headquarters
4050 Azalea Drive
CHARLESTON SC 29405

Re: K070755
Trade/Device Name: Avreo InterWorks™ System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 1, 2007
Received: March 19, 2007

Dear Ms. Butcher:

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 (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): N/A K070755

Device Name: Avreo InterWorks™ System

Indications for Use:

InterWorks™ product is intended to provide a completely scalable PACS solution for hospitals and other related sites, which will distribute, retrieve archive, and display, data and images from a variety of different modality and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation", and will include standard features and other Mammo tools. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Application areas include imaging centers, radiologist central reading rooms and any other locations where trained medical professionals would require access or desire patient images, demographic information or other patient medical information captured in the system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over the Counter Use _____

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070755