

K141556
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4050 Azalea Drive, N. Charleston, SC
29405

JUL 02 2014

510(k) Summary

I. Date Prepared: 02/20/2014

II. Submitter:

Avreo, Inc.
4050 Azalea Drive
North Charleston, SC 29405
Fax: 843-571-5996

III. Contact Person:

Alison McKee
Marketing Manager
Avreo, Inc.
866-286-8082

IV. Device Name:

Trade Name: interWORKS
Common Name: interWORKS
Classification Name: Picture Archiving and Communications System (PACS) (21 CFR 892.2050, Product Code LLZ)

V. Predicate Device:

K070755
interWORKS
Class II
Decision Date: 05/08/2007

VI. Device Description and Label:

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, stores, 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.

VII. Intended Use:

interWORKS 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 cleared display that meets technical specifications reviewed and accepted by 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.

VIII. Comparison of Characteristics:

The modified picture archiving and communications systems (PACS) has the following similarities to those which previously received the 510(k) concurrence:

- Have the same indicated use,
- Use the same operating principle,
- Incorporate the same basic development design, and
- Incorporate the same basic workflow design.

The only modifications that were made are:

- Ability to store lossy compressed images for non-mammography studies.

IX. Tests:

Avreo, Inc. follows the 21 CFR 820 for design control. To test the modifications made to interWORKS, we completed a regression test.

X. Conclusion:

Avreo, Inc. believes that sufficient information is included to reach a determination of substantial equivalence. We conclude that the interWORKS is as safe and effective as the predicate device, and that the technological characteristics demonstrate that they are equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AVREO, INC.
ALISON MCKEE
4050 AZALEA DR
N CHARLESTON SC 29405

July 2, 2014

Re: K141556

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: June 6, 2014
Received: June 12, 2014

Dear Ms. McKee:

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

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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)

K141556

Device Name

Avreo interWORKS System

Indications for Use (Describe)

interWORKS 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 cleared display that meets technical specifications reviewed and accepted by 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.

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)



This section applies only to requirements of the Paperwork Reduction Act of 1995.

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