K073272

5. 510(k) Summary (as required by section 807.92(c))

5.1. 510(k) Submitter

510(k) owner's name: Three Palm Software, LLC

Address: 367 Penn Way, Los Gatos, CA 95032 USA

Phone: 408-356-3240

DEC 1 1 2007

Name of contact person: Heidi Daoxian Zhang

Date the summary was prepared: November 19, 2007

5.2. Device Name

Trade name: WorkstationOne™ Breast Imaging Workstation

Common name: Picture archiving and communications system

Classification name: System, Image Processing, Radiological (21 CFR 892.2050 Product Code LLZ)

5.3. Predicate Devices

WorkstationOne™ Breast Imaging Workstation is substantially equivalent to the devices listed below:

Trade Name	Manufacturer	510(k) Number
Seno Advantage	General Electric Medical Systems	K033400
Cedara I-ReadMammo	Cedara Software Corp.	K040468
Secta Workstation	Sectra Imtec AB	K063093

5.4. Device Description

The WorkstationOne™ is a diagnostic breast imaging workstation which consists of a software system that obtains breast imaging screening or diagnosis exams from PACS or Modalities; displays and manipulates the images for radiologists to perform interpretation task. The workstation also supports media exchange and film printing. Optionally, the workstation can interface with a reporting system to generate an interpretation report.

The enterprise workflow of the workstation follows IHE integration profiles, specifically, MAMMO (Mammography Image Profile) and RWP (Reporting Workflow Profile). The workstation can be configured to use mammographic specific hanging protocol and reading workflow. The workstation obtains the source images and CAD reports either as the recipient of the push of that data, or by querying and retrieving them from a PACS archive. In both models, DICOM is used. The images can only be the lossless compressed or non-compressed DICOM images.

The WorkstationOne™ is a software system that can be installed on an off-the-shelf general-purpose computer with one or two gray-scale high-resolution monitors and one color monitor. The high-resolution monitors are used to display digital mammography images and associated overlays for the purpose of primary interpretation by radiologists. The color monitor is used for selecting studies, displaying color images, navigating workflow, and other user interface elements. Optionally, a dedicated keypad or touchpad is included for ergonomic reasons.

5.5. Indications for Use

The WorkstationOne™ Breast Imaging Workstation is intended for use with a regionally approved digital mammography system. The workstation displays images from multiple modalities, which include X-ray mammography MG, breast US and breast MRI. The workstation allows selection, display, manipulation, quantification, markup, print composition and media exchange of breast images. Here, quantification refers to measurements (such as area and distance) within a region of interest that the radiologist manually draws on the images. Similarly, markup refers to graphics that are manually drawn by the radiologist to indicate a region of interest. Note that the region of interest is not automatically generated by the computer.

The WorkstationOne™ Breast Imaging Workstation is intended for softcopy reading and interpretation of digital mammography images by Radiologists.

The WorkstationOne™ Breast Imaging Workstation when used for interpretation of images acquired using a FFDM image acquisition system shall display the images only on FDA-cleared high-resolution monitors. The images used for primary diagnostic reading must be in a lossless format, unless lossy formats are approved for use in digital mammography.

5.6. Technological Characteristics Comparison

WorkstationOne™ Breast Imaging Workstation has the similar technological characteristics to the equivalent devices as all support radiology workflow integration, obtaining, displaying, and manipulating of MG, US or MR images. Both the WorkstationOne™ Breast Imaging Workstation and the Sectra Workstation allow displaying of CAD reports.

5.7. Non-clinical Test

The potential hazards have been studied and controlled by a Risk Management Plan. The software testing procedure has been developed. The procedure with pass/fail criteria has been run to ensure that the product meets all the specified requirements.

5.8. Conclusions

The materials provided in this 510(k) submission have demonstrated the device is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2007

Ms. Heidi Daoxian Zhang
Vice President, Clinical Affairs
Three Palm Software, LLC
367 Penn Way
LOS GATOS CA 95032

Re: K073272
Trade/Device Name: WorkstationOne™ Breast Imaging Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 19, 2007
Received: November 21, 2007

Dear Ms. Zhang:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

4. Indications for Use Statement

510(k) Number (if known): K073272

Device Name: WorkstationOne™ Breast Imaging Workstation

Indications for Use:

The WorkstationOne™ Breast Imaging Workstation is intended for use with a regionally approved digital mammography system. The workstation displays images from multiple modalities, which include X-ray mammography MG, breast US and breast MRI. The workstation allows selection, display, manipulation, quantification, markup, print composition and media exchange of breast images. Here, quantification refers to measurements (such as area and distance) within a region of interest that the radiologist manually draws on the images. Similarly, markup refers to graphics that are manually drawn by the radiologist to indicate a region of interest. Note that the region of interest is not automatically generated by the computer.

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073272