K110040

JAN 2 6 2011

Modern Module

510 (K) Summary

Summary of functions of the device and its major components provided as part of the Premarket Notification for OmniVision

Date : 30 March 2010
Company Name : Modern Module Inc.
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Device Trade Name: OmniVision
Device Common Name : Picture Archiving and Communications System (PACS)
Product Code : LLZ
Regulation Number 892.2050
Device Classification : Class II
Predicate Devices dicomPACS

Predicate Devices	
Trade Name	dicomPACS
Common Name	Picture Archiving and Communications System (PACS)
Regulation Number	892.2050
Device Classification	Class II
Product code	LLZ
Manufacturer	Oehm und Rehbein GmbH
510(k) number	K070618

Comparison between the Predicate Device and the OmniVIsion

Items	Predicate Device	Subject Device	Remark
510(k) No.	K070618		
Trade Name	dicomPACS	OmniVision	
Indications for use	*dicomPACS®* is a software system for the administration, archiving, improvement and compression of medical image data for diagnosis. The images are either acquired from imaging modalities via DICOM or imported dir3ectly. All images are archived in a database as DICOM compliant files. The data is displayed on a computer monitor for diagnosis. *dicomPACS®* also provides services for administering the data. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA. Functions to be carried out using *dicomPACS®* are, for example, but not limited to, adjustment of window leveling, rotation, zoom,	OmniVision is intended to be used for the acquisition, storage, communication and viewing of medical Images. OmniVision receives images from imaging modalities via DICOM or imported directly. It archives and displays these images for the use of medical specialists who are qualified to operate radiological equipment and to record and diagnose medical images. It provides the user with a range of tools to assist them in viewing the images, such as zoom, filters and measurements, and with facilities to exchange images with other specialists. OmniVision is not intended for the acquisition of mammographic image data.	

	and measurements. *dicomPACS®* is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data.		
Product Availability	Available now	Available now	Similarity
System			
Architecture	Server & Client, Web-based versions, local servers & remote archiving	Server & Client, Web-based versions, local servers & remote archiving	Similarity
Operating System	Window XP	Window XP	Similarity
Hardware	HP, Dell, IBM	HP, Dell, IBM	Similarity
Administration			
System failure Alert	Available	Available	Similarity
DICOM Compatibility			
DICOM Worklist	Yes	Yes	similarity
DICOM Storage	Yes	Yes	similarity
DICOM Printer	Yes	Yes	Similarity
Image Acquisition			
Image Acquisition	DICOM radiology systems Digital film scanner Other imaging modalities	DICOM radiology systems Digital film scanner Other imaging modalities	Similarity
Image Manipulation			
Rotation	Yes	Yes	similarity
Invert	Yes	Yes	similarity
Zoom In/Out	Yes	Yes	similarity
W/L Adjustment	Yes	Yes	similarity
Pan Image	Yes	Yes	similarity
Flipping	Yes	Yes	similarity
Image Crop	No	Yes	

Image Post-Processing			
Secondary Processing	Organ specific type	Organ Specific Type	similarity
Measurement			
Length Measurement	Yes	Yes	similarity
Angle Measurement	Yes	Yes	similarity
Multiple Length Measurement	Yes	Yes	similarity
Backup			
Storage Backup method	CD/DVD, Flash Drive	CD/DVD, Flash Drive, URL	
Export Format	DICOM, TIFF, BMP, JPEG, PNG	DICOM, BMP	
Services			
Support	24/7 customer support for application software.	24/7 customer support for application software.	similarity
Training	On/off site available	On/off site available	similarity

Description:

OmniVision is a Picture Archiving and Communications System (PACS), as is the predicate Device dicomPACS. All of them have been developed to acquire, store, communicate, display and process medical images. They offer features (e.g. window leveling, zoom, measurements, annotations etc.) routinely used by medical professionals, such as radiologists and orthopaedists, and required of all PACS solutions.

OmniVision has a modular system architecture, It consists of the basic application viewer for image viewing and processing, image storage and communication, and a number of other modules for database management, image acquisition, printing etc.

OmniVision conforms to the DICOM (Digital Image and Communications in Medicine) standard.

Indications for Use:

OmniVision is intended to be used for the acquisition, storage, communication and viewing of medical images.

OmniVision receives images from modalities via DICOM or imported directly. It archives and displays these images for the use of medical specialists who are qualified to operate radiological equipment and to record and diagnose medical images. It provides the user with a range of tools assist them in viewing the images, such as zoom, filters and measurements, and with facilities to exchange images with other specialists.

OmniVision is not intended for the acquisition of mammographic image data.

Technological Characteristics:

OmniVision is intended to be used for the acquisition, storage, communication and viewing of medical images. OmniVision is an autonomous software and involves no hardware. This largely applies to the predicate device dicomPACS.

OmniVision receives images from modalities via DICOM or imported directly. It archives and displays these images for the use of medical specialists who are qualified to operate radiological equipment and to record

and diagnose medical images. It provides the user with a range of tools assist them in viewing the images, such as zoom, filters and measurements, and with facilities to exchange images with other specialists.

OmniVision does not control any life-sustaining devices. Specialists with adequate expert knowledge for competent human intervention interpret displayed or printed images and information.

OmniVision runs on any hardware platform meeting the minimum system requirements.

OmniVision can be used with the server operating systems MS Windows XP

Testing:

Omnivision has been tested according to the specifications documented in this notification. It conforms to the DICOM standard as laid out in the included DICOM Conformance Statement.(Tab. 9 section 2)

Conclusion:

Omnivision is a medical device. OmniVision provides functionality comparable to that of its Predicate Device, dicomPACS and is intended for the same user and patient groups as its Predicate Device.
Based on the indications for use, Technological Characteristics, performance testing and comparison to predicate device, the proposed OmniVision is substantially equivalent and has been shown to be safe and effective for its intended use

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

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Engineering Leader
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JAN 2 6 2011

Re: K110040
Trade/Device Name: OmniVision
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 10, 2010
Received: January 6, 2010

Dear Mr. Mouser:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110040

Device Name: **OmniVision**

Indications for Use:

OmniVision is intended to be used for the acquisition, storage, communication and viewing of medical Images.OmniVision receives images from imaging modalities via DICOM or imported directly. It archives and displays these images for the use of medical specialists who are qualified to operate radiological equipment and to record and diagnose medical images.

It provides the user with a range of tools to assist them in viewing the images, such as zoom, filters and measurements, and with facilities to exchange images with other specialists.

OmniVision is not intended for the acquisition of mammographic image data.

Prescription Use ___X____ (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 OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K110040