K01 3878

DEC 0 7 2001

510(k) Summary

1. Company Identification

CyberMed, Inc.
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2. Official Correspondent

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3. Date of Submission

November 14, 2001

4. Device Name

Classification Name:	Picture Archiving and Communications System (PACS)
Common/Usual Name:	Image processing, management and 3D visualization system
Proprietary Name:	CyberMed, Inc., **V-works™**

5. Substantial Equivalence

The CyberMed Inc., V-works™ is substantially equivalent to the Voxar Limited Plug'n View 3D, 510(k) #992654.

6. Device Description and Intended Use

The **V-works™** is a software application for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI or 3D Ultrasound. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print and distribute DICOM 3.0 complaint image studies, utilizing standard PC hardware. All of the functions are supported on standard personal computer platform for ease of cost and maintenance. The use of Microsoft Windows 98/ME/2000 Professional/NT 4.0 operating system makes the **V-works™** software easy to use and capable of being integrated with other computer needs.

7. Software

CyberMed, Inc., certifies that the **V-works™** is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

8. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes, and their effects;
- Development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components . These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

9. Safety Concerns

The hardware is "off-the-shelf" and complies with applicable electrical safety standards for standard PC hardware and peripherals.

10. Substantial Equivalence

The following product provides functions, which are substantially equivalent to this product:

Characteristics	CyberMed,Inc. V-works™	PREDICATE DEVICE Voxar Limited Plug'n View 3D
510(k) number		K992654
Type of Software Program	Stand alone application program	Stand alone application program
Computer Platform	Pentium II or III with Windows 98 / ME / NT 4.0 / 2000 Professional	Pentium III with Windows NT 4.0 / Windows 2000 professional
Communications	TCP/IP	TCP/IP
DICOM compliance	DICOM 3.0 compliance for CT, MRI or 3D Ultrasound images	DICOM 3.0 compliance for CT, MRI,NM,CR,SC and Ultrasound (single frame) images
Image Format In	ACR NEMA 2.0 , BMP, DICOM 3.0	ACR NEMA 2.0, DICOM 3.0
Image Format Out	BMP, JPEG, DICOM 3.0	DICOM 3.0
Image Archive	SCSI 2-20 Gbytes, CD-ROM	SCSI 2-20 Gbytes, CD-ROM
Image Display	Color / Greyscale, CRT or Laptop LCD 1024×768 or higher, 8, 16 or 24 Bits	Color / Greyscale, CRT or Laptop LCD
Image Processing	Window Level, Pan, Zoom, Rotate, and Flip	Window Level, Pan, Zoom, Rotate, Flip and cine
Image Edit	Manual Segmentation by drawing a contour (slice edit, region edit, VOI edit), Semi-automatic Segmentation (Snake), Volume Sculpting, Segmentation by CT number threshold, Multi-tissue Opacity Control, Other Segmentation (Selecting object, Boolean operation, Dilate/Erode)	Advanced Segmentation Volume Sculpting Multi-tissue Opacity Control
Volume Rendering	Maximum, or Minimum Intensity Projection (MIP, MinIP) Radiographic Projection, Color Rendering, Surface Rendering, Quick Surface Rendering, Volume Rendering, Multi-planar Reconstruction (MPR), Virtual Endoscopy	interactive opacity / transparency control, clipping volume of interest(VOI), zoom, pan and rotate
Measurements	2D measurement tools including distance, angle, and area. 3D measurement tools including volume, distance and angle	2D measurement tools including distance, angle and ROI statistics, 3D volume measurement
Printing	Printing to standard Windows printers	Printing to standard Windows printers
Prescriptive Device	Same as predicate.	Prescription use only

Discussion of the similarities and differences and an explanation of important differences between V-works and Plug'n View 3D

1. Similarities between V-works ™ and Plug'n View3D

The similarities between V-works ™ and Plug'n View3D are as follows;

Manufacturer:	**Cybermed,Inc.**	**Voxar Limited**
Product Name:	**V-works ™**	**Plug'n View3D**
Computer Platform	Same as right column	Pentium III with Windows NT 4.0 / Windows 2000 professional
Communications	Same as right column	TCP/IP
DICOM compliance	Same as right column	DICOM 3.0 compliance for CT, MRI,
Image Format In:	Same as right column	ACR NEMA 2.0, DICOM 3.0
Image Format Out:	Same as right column	DICOM 3.0
Image Archive	Same as right column	SCSI 2-20 Gbytes, CD-ROM
Image Display	Same as right column	Color / Greyscale, CRT or Laptop LCD
Image Processing	Same as right column	Window Level, Pan, Zoom, Rotate, Flip
Image Edit	Same as right column	Advanced Segmentation Volume Sculpting Multi-tissue Opacity Control
Measurements	Same as right column	2D measurement tools including distance, angle,
Printing	Same as right column	Printing to standard Windows printers

V-works ™ and Plug'n View 3D are redefining the concept of medical imaging with its quick, easy-to-use, easy-to-integrate, and affordable PC-based software. V-works ™ and Plug'n View 3D allow the rapid display of CT and MR data on PC, laptop or PACS Workstation.
In addition, V-works ™ and Plug'n View 3D are increasing access to this technology for radiologists and referring clinicians, leading to better communication of results, improved workflow and faster and more accurate diagnosis.

2. Differences between V-works ™ and Plug'n View3D

The differences between V-works ™ and Plug'n View3D are as follows;

Manufacturer:	Cybermed,Inc.	**Voxar Limited**
Product Name:	**V-works ™**	**Plug'n View3D**
510(k) number	Unknown	K992654
DICOM compliance	3D Ultrasound images	None
Image Format In:	BMP	None
Image Edit	Manual Segmentation by drawing a contour (slice edit, region edit, VOI edit), Semi-automatic Segmentation (Snake), Other Segmentation (Selecting object, Boolean operation, Dilate/Erode)	None
Volume Rendering	Radiographic Projection, Surface Rendering, Quick Surface Rendering, Virtual Endoscopy	None
Measurements	3D measurement tools including volume, distance and angle	None

V-works ™ has function of Surface Rendering (SSD) and Virtual Endoscopy, but Plug'n View3D does not function of them. The specifications of Surface Rendering (SSD) and Virtual Endoscopy are as follows;

1) Surface Rendering (SSD; Shaded Surface Display)
   - Quick SSD (Shaded Surface Discplay)
   - 3D operation
   - Import / Export 3D model

2) Virtual Endoscopy mode
   - Displaying current camera position on classic MPR images
   - Free navigation using keyboard and mouse
   - Creation of navigation path semi-automatically on 3D external view Creation of navigation path manually on 3D internal view Displaying a path and camera angle and camera position on external view
   - Exporting AVI file of navigation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

CyberMed, Inc.
% Mr. Justin Gagnon
Associate Project Manager
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K013878
Trade/Device Name: CyberMed Inc., V-Works
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 21, 2001
Received: November 23, 2001

Dear Mr. Gagnon:

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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K01 3878

Device Name: CyberMed, Inc., V-works

Indications for use:

The V-works is a software application for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI or 3D Ultrasound. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print and distribute DICOM 3.0 compliant image studies, utilizing standard PC hardware.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013878

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____