K053281

DEC 7 2005

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, Emageon Inc. is providing a summary of safety and effectiveness information regarding the EVMS™: Enterprise Visual Medical System software.

1.1 Company Identification

Emageon Inc.
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Suite 400
Madison WI 53703
Establishment Registration Number: 2135350
Contact: Inger Hanson
Tel: 608 256 7775
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1.2 Official Correspondent

Inger L. Hanson
Director of Quality and Regulatory Affairs
Emageon Inc.
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Establishment Registration Number: 2135350
Tel: 608 256 7775
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Email: Inger.Hanson@emageon.com

1.3 Date of Submission

October 31st, 2005

1.4 Device Name

Classification Name:	Image Processing System, 21 CFR §892.2050, ProCode LLZ
Common/Usual Name:	Picture Archiving and Communication System
Proprietary Name:	EVMS™ (formerly Ultravisual™)

Cleared Device(s): Vortex™ , 510(k): K012097, Ultravisual™, 510(k) K042008

1.5 Device Description and Intended Use

Emageon Inc.'s EVMS™ software is integrated client-server software package comprised of features that were previously cleared in Vortex™, 510(k): K012097, and Ultravisual™, 510(k) K042008. The main difference is that the software will now allow display Standard Uptake Value measurements, MPR on irregular data sets and in oblique planes, and automatic region growing, the naming conventions of the components have been modified, the design architecture and the overall design and development process in order to synchronize the existing compliance to the federal QSR 21 CFR, Part 820 with ISO 13485:2003 and ISO 14971:2000/Amd 1.:2003(E).

1.6 Software Development

Emageon Inc. certifies that the EVMS™ software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications ad designs, coding and unit testing, validation testing and field maintenance. These procedures are documented in accordance with the Federal QSR, 21, CFR, Part 820 and with ISO 13485:2003 and ISO 14971:2000/Amd 1.:2003(E) . Emageon Inc. holds ISO 13485:2003 UKAS and CMDCAS quality system certificates for both the Madison, WI and Birmingham, AL locations.

1.7 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use.

The hardware components specified (and/or optionally supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software package has been performed by programmers, non-programmers, quality assurance staff, potential customers, and contracted third parties.

Substantial Equivalence:

The intended use of Emageon Inc.'s EVMS™ software is substantially equivalent in the opinion of Emageon Inc. to the feature set described in the original Vortex™ software, 510(k) K012097; Ultravisual™ software, 510(k) K042008 and do not pose any new issues of safety and effectiveness.

1.8 Substantial Equivalence Chart

Product Name	UltraVisual Vortex™	Emageon UV, Inc., Ultravisual	Emageon Inc. EVMS™
Indications For Use	The system is designed to provide image storage, display, and workflow integration capabilities for healthcare enterprises. The image display architecture provides workgroup diagnostic viewing capabilities for radiologists as well as image reviewing functionality for referring physicians and other clinicians. In addition to traditional 2D image viewing functionality, the image display system provides advanced 3D features including volume rendering and multi-planar reconstruction designed to function in web-enabled viewers over both local and wide area networks. Intended users of the image distribution system include radiologists, referring physicians, tertiary	Same with the addition of viewing presentation quality digital mammography images sent via the DICOM standard as documented in the Indications for Use.	Same with the addition of Standard Uptake Value Display, Display of oblique planes in MPR mode and display of MPR on Irregular data sets, automatic region growing, and component renaming.

	care physicians, medical technologists, and information technology professionals.		
Windows O.S. – Client	Yes	Same	Same
Uses Standard. Monitor	Yes	Same	Same
Scales Image to Display.	Yes	Same	Same
Image Input	DICOM 3.0	Same	Same
Images stored on remote NT server	Yes	Same	Same
Network Protocol	TCP-IP	Same	Same
Compression	Wavelet/JPEG	Same	Same
Image Measurement	Yes	Same	Standard Uptake Value Added
Cine tool	Yes	Same	Same
Comparison Mode	Yes	Same	Same
Flip / Rotate of Images	Yes	Same	Same
Patient & Study Browser	Yes	Same	Same
Volume Rendering	Volume rendering with interactive opacity/ transparency control, clipping volume of interest (VOI), zoom, pan and rotate	Same	Same
Multi-Planar Reformatting (MPR)	MPR into any user-defined linear plane.	Same	Added Oblique planes and Irregular data sets.
Maximum Intensity Projection (MIP)	MIP with interactive window-level, clipping VOI, zoom, pan and rotate	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 2005

Emageon, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K053281
Trade/Device Name: EVMS™ Enterprise Visual Medical System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 21, 2005
Received: November 25, 2005

Dear Mr. Job:

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.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" (21 CFR 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 (301) 443-6597 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

Indications for Use

K053281

510(k) Number (if known): Vortex™: K012097; IVMS: UltraVisual™: K042008

Device Name: EVMS™ Enterprise Visual Medical System

Indications For Use:

The **Enterprise Visual Medical System(TM)** is classified as a picture archive and communications system. It is a software only solution developed by Emageon Inc., combined with other 3rd party off the shelf software, standard computer workstations and standard storage devices that allow authorized physicians and authorized healthcare professionals to manage, access, visualize and store digital medical images, and data associated with the images, across the enterprise using advanced visualization tools, clinical content management and clinical workflow through a graphical user interface.

Advanced Visualization (Image Viewing) includes: Full featured 2D imaging, 3D surface and volume rendering, Real-time Multi-Planar Reformatting (MPR), Real-time oblique imaging, Integrated image fusion, JPEG2000-based Adaptive Bandwidth Streaming, JPEG and Key Image Note export, Presentation States, Annotation and measurement tools, Automated linking, Display protocols, Enterprise Worklist, prior study management, softcopy viewing of digital mammography images provided that only *5 MP monitors with a cleared 510(k)* are used *and that digitized secondary captures of these images are not viewed for assisting in diagnosis*, utilization of third-party electronic orthopedic templates, the display of Standard Uptake Value, recording voice reports using third party, plug-in software, and user configurable settings for viewing digital medical images and corresponding data.

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

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053281