K051809

EasyViz

Medical Insight

AUG 15 2005

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, Medical Insight, is providing a summary of safety and effectiveness information regarding the *EasyViz* software.

1.1 Company Identification

Medical Insight A/S
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1.2 Official Correspondent

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Regulatory Management Services
16303 Panoramic Way
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1.3 Date of Submission

June 30, 2005

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Soft-copy reading system
Proprietary Name:	EasyViz(tm)

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1.5 Substantial Equivalence

The EasyViz(tm) has the same intended uses and technical characteristics as the Stentor iSite Radiology System, (K042292) and the Terarecon Aquarius Workstation and Aquariusnet (K011142 and K012086 respectively).

1.6 Device Description and Intended Use

The EasyViz(tm) system is designed as a diagnostic reading workstation system, which will be packaged with standard PC hardware and optionally, pocket PCs (PDAs) for use by referring physicians.

EasyViz(tm) is capable of receiving and displaying DICOM images.

Images sent to EasyViz(tm) are converted into formats suitable for viewing in its framework, and are temporarily stored in a local cache (memory). The algorithms used by EasyViz(tm) to create JPEG and wavelet images follow known and accepted protocols.

Images sent to EasyViz(tm) can be viewed using an executable program that is installed on a Personal Computer or other devices equipped with the appropriate hardware.

EasyViz(tm) uses standard "off-the-shelf" PC hardware and communicates using the standard TCP/IP stack. The network hardware used to support the TCP/IP stack is superfluous to EasyViz(tm).

1.7 Software Development

Medical Insight certifies that the EasyViz(tm) system is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization

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responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic quality images and associated information to the intended users.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

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

The optional hardware components specified are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software and hardware have been performed by programmers, by non-programmers, quality control staff, and by potential customers.

Substantial Equivalence:

The EasyViz(tm) Client is a software package used to receive images from the EasyViz(tm) Server. It provides the user Diagnostic quality images and the tools to make a diagnosis.

EasyViz(tm) is substantially equivalent to the Stentor iSite Radiology System, (K042292) and the Terarecon Aquarius Workstation and Aquariusnet (K011142 and K012086 respectively).

It is our conclusion that there is no software component in the EasyViz(tm) product, or hardware component which would be used in conjunction with the EasyViz(tm) product, that we know of whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus the "Level of Concern" of the EasyViz(tm)

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product is "minor".

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1.9 Substantial Equivalence Chart

Product Name	Medical Insight EasyViz	TeraRecon Aquariusnet	TeraRecon Aquarius Workstation	Stentor-ISite Radiology
Print to Paper Capability	Yes	Yes	Yes	Yes
Graphical UI	Yes	Yes	Yes	Yes
Windows O.S. - Client	Yes	Yes	Yes	Yes
Uses Standard. Monitor	Yes	Yes	Yes	Yes
Scales Image to Display.	Yes	Yes		Yes
Image Input	DICOM 3.0	DICOM 3.0	DICOM 3.0	DICOM 3.0
Images stored on remote NT server	Yes	Yes	Yes	Yes
Network Protocol	TCP-IP	TCP-IP	TCP-IP	TCP-IP
Compression	Proprietary	Proprietary	Proprietary	Wavelet
Annotation	Yes	Yes	Yes	Yes
Image Measurement	Yes	Yes	Yes	Yes
Cine tool	Yes	Yes	Yes	Yes
Comparison Mode	Yes	Yes	Yes	Yes
Review Report from RIS	Yes	Yes	Yes	Yes
Designed for Use Inside and Outside of Radiology	Yes	Yes	Yes	Yes
Flip / Rotate of Images	Yes	Yes	Yes	Yes
User Log In	Yes	Yes	Yes	Yes
Multiple Layout Options	Yes	Yes	Yes	Yes
WW/WL control & Pre-sets	Yes	Yes	Yes	Yes
Patient & Study Browser	Yes	Yes	Yes	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Medical Insight A/S
% Mr. Gary J. Allsebrook
Official Correspondent
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578-1116

Re: K051809
Trade/Device Name: Medical Insight, EasyViz™ PACS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 30, 2005
Received: July 5, 2005

Dear Mr. Allsebrook:

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

K051809

Device Name: Medical Insight, *EasyViz*™ PACS System

Indications For Use:

The Medical Insight *EasyViz*™ PACS System is a Diagnostic Softcopy Reading software package to be used for primary diagnosis and clinical review of digital radiology images.

The product utilizes the conventional TCP/IP internetworking infrastructure available in most healthcare organizations, and it uses commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows XP, Linux).

The product interfaces to existing imaging equipment using the DICOM PS 3.1-2000 (Digital Imaging And Communications In Medicine) standard communication protocol as described and developed by ACR.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 M-pixel resolution and meets other technical specifications reviewed and accepted by the US FDA.

The system does not permanently store or produce original medical images.

(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____
(Per 21 CFR 901.109)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051809