K061696

EXHIBIT 2

NOV 13 2006

EDDA Technology 510(k) Summary

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Contact: Xiaolan Zeng, Vice President
Date prepared: May 25, 2006

1. Identification of the Device:
   Proprietary – Trade Name: IQQA-Liver Software
   Classification Name: System, Image Processing, Radiological, Product Code LLZ
   Common/Usual Name: Radiological Image Processing System

2. Equivalent legally marketed devices:

Manufacturer	Name of the Predicate Device	FDA 510(k) Number	FDA Clearance Date
Mevis Technology GMBH & CO.KG	Mevis LiverAnalyser / LiverViewer Software	K051528	07/20/2005
GE Medical Systems	Volume Viewer Plus	K041521	06/22/2004

3. Indications for Use (intended use): The IQQA-Liver is a PC-based, self-contained, non-invasive image analysis software application for reviewing serial multi-phase CT acquisitions of the liver. Combining image viewing, processing and reporting tools, the software is designed to support physicians in the visualization, evaluation and reporting of liver and physician-identified liver lesions. The software supports a workflow based on automated image registration for viewing and analyzing multi-phase volume datasets. It also includes tools for interactive segmentation and labeling of liver segments and vascular structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, and allows for regional volumetric analysis of such lesions in terms of size, shape, position and enhancement pattern, providing information for physician's assessment of lesion characterization. The software is designed for use by trained physicians. Image source: DICOM.

4. Description of the device: The IQQA-Liver Software is a self-contained, non-invasive radiographic image analysis application that is designed to run on standard PC hardware. The image input is DICOM. Combining image processing, viewing and reporting tools, the software supports physicians in the visualization, evaluation and reporting of liver and physician identified liver lesions. Viewing tools include 2D axial image viewing, window level adjustment, a pre-defined optimized liver window level setting, synchronized viewing of multi-phase datasets, MPR and MIP. Analysis and evaluation tools include segmentation of structures utilizing user input of seeding points, interactive labeling of segmented areas, quantitative measurement derived from segmentation and labeling results, and the measurement of distance between physician specified structures to landmarks. Reporting

tools in the software automatically assemble information (including physician identified lesion locations, measurement information, physician-input lesion characterization, lesion ROI images across multi-phases, and illustrative snapshots of the GUI taken by physicians) for physician's confirmation and for further diagnosis note input. The IQQA-Liver software supports a workflow based on automated registration for viewing and analyzing multi-phase volume datasets. The software automatically matches the spatial location of axial images across multi-phases, and provides synchronized viewing of multi-phase dataset to aid visualization. The software further includes tools for interactive segmentation and interactive labeling of liver segments and vascular structures (such as liver lobes, vessels and major branches), thus facilitating the visualization of spatial relationship between suspicious liver lesions and specified anatomical structures/landmarks. The tools also allow for interactive segmentation of physician-identified lesions using user input of seed points, and regional analysis of such lesions with respect to size, shape, position and enhancement pattern, thus providing information to help physician's assessment of lesion characterization. The software is designed for use by trained physicians only. Physicians make all final patient management decisions.

5. Safety and Effectiveness, comparison to predicate devices:

	Device of 510(k) submission: **IQQA-Liver Software**	*Predicate Device:* Mevis LiverAnalyser /LiverViewer software **K051528**	*Predicate Device:* **Volume Viewer Plus K041521**
Manufacturer	EDDA Technology, Inc.	Mevis Technology GMBH & CO.KG	GE Medical Systems
Indications for Use	The IQQA-Liver is a PC-based, self-contained, non-invasive image analysis software application for reviewing serial multi-phase CT acquisitions of the liver. Combining image viewing, processing and reporting tools, the software is designed to support physicians in the visualization, evaluation and reporting of liver and physician-identified liver lesions. The software supports a workflow based on automated image registration for viewing and analyzing multi-phase volume datasets. It	The Mevis LiverAnalyzer / LiverViewer SoftwareTM device is intended for preoperative planning in liver surgery. The device is used to analyze data and to display image analysis and risk analysis results for the preoperative planning in liver surgery, e.g. organ segmentation, tumor segmentation, segmentation of intrahepatic vessels as well as the approximation of vascular territories. Preoperative evaluation of specific surgery strategies is supported by the feature to interactively define virtual resections splitting	Volume Viewer Plus is medical diagnostic software that allows the processing, review, analysis and communication of 3D reconstructed images and their relationship to originally acquired images from CT, MR, X-Ray Angio and PET scanning devices. The combination of acquired images, reconstructed images, annotations and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information for diagnosis, surgery and treatment planning.

	also includes tools for interactive segmentation and labeling of liver segments and vascular structures. The software provides functionalities for manual or automated segmentation of physician-identified lesions, and allows for regional volumetric analysis of lesions in terms of size, shape, position and enhancement pattern, providing information for physician's assessment of lesion characterization. The software is designed for use by trained physicians. Image source: DICOM.	the liver or to calculate safety margins around lesions identifying affected vascular branches and vascular territories supplied or drained by these branches. Medical image data is derived from various sources (i.e. CT scanners, MRI scanners). Typical users of this system are trained professionals, including physicians, nurses, and technicians.	
Hardware Configuration	standard PC hardware	standard PC hardware	standard PC hardware
User Interface	A graphical user interface for users to interact with the software, select tools and drive workflow	A graphical user interface for users to interact with the software, select tools and drive workflow	A graphical user interface for users to interact with the software, select tools and drive workflow

6. Testing Information and Conclusion

   In all material respects, the IQQA-Liver Software is substantially equivalent to the predicate systems. Testing was performed according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

EDDA Technology, Inc.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

NOV 1 3 2006

Re: K061696
Trade/Device Name: IQQA-Liver Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 23, 2006
Received: October 30, 2006

Dear Mr. Conry:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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

Indications for Use

510(k) Number (if known): K061696

Device Name: IQQA-Liver Software

The IQQA-Liver is a PC-based, self-contained, non-invasive image analysis software application for reviewing serial multi-phase CT acquisitions of the liver. Combining image viewing, processing and reporting tools, the software is designed to support physicians in the visualization, evaluation and reporting of liver and physician-identified liver lesions.

The software supports a workflow based on automated image registration for viewing and analyzing multi-phase volume datasets. It also includes tools for interactive segmentation and labeling of liver segments and vascular structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, and allows for regional volumetric analysis of such lesions in terms of size, shape, position and enhancement pattern, providing information for physician's assessment of lesion characterization.

The software is designed for use by trained physicians. Image source: DICOM.

Prescription Use X ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061696