K131498
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EDDA Technology 510(k) Summary
5 Independence Way
Princeton, NJ 08540
Tel: 609-919-9889
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Contact: Xiaolan Zeng, Executive Vice President
Date prepared: May 21, 2013

JUL 2 5 2013

1. Identification of the Device:
   Proprietary – Trade Name: IQQA-Liver Multimodality 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
GE Medical Systems	Volume Viewer Plus	K041521	06/22/2004
Mevis Technology GMBH & CO.KG	Mevis LiverAnalyser / LiverViewer Software	K051528	07/20/2005
EDDA Technology	IQQA-Liver Software (v1.0)	K061696	11/13/2006
Pathfinder Therapeutics	PlaniSight Linasys	K082228	09/22/2008

3. Indications for Use (intended use):

IQQA-Liver Multimodality is a PC-based, self-contained, non-invasive image analysis software application for reviewing multiphase images derived from various sources (e.g. CT scanners, MR scanners). Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation and reporting of liver and physician-identified lesions.

The software supports a workflow based on automated image registration for viewing and analyzing multiphase volume datasets. It 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, interactive definition of virtual resection plane, and allows for regional volumetric analysis of such lesions in terms of size, position, margin and enhancement pattern, providing information for physician's evaluation and treatment planning.

The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.

4. Description of the device: The IQQA-Liver Multimodality Software is a self-contained, non-invasive radiographic image analysis application that is designed to run on standard PC hardware. The image data utilized is derived from sources including CT and MR scanners, and of DICOM format. Combining image processing, viewing and reporting tools, the software supports the visualization, evaluation and reporting of liver and physician identified liver lesions. Viewing tools include various standard visualization modes (e.g. original DICOM 2D image viewing, window level adjustment, synchronized viewing of multi-phase sets, Multi-Planar Reformation (MPR) in any plane (orthogonal, oblique, curved), 3D views in rendering

mode (MIP, MinIP, volume rendering), and their relationship to originally acquired images from modality). Analysis and evaluation tools include segmentation of structures utilizing user input of seeding points, user tracing and interactive editing, interactive labeling of segmented areas, quantitative measurement derived from segmentation and labeling results, and the measurement of distance between physician specified structures and 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, information of liver lobes and vessels, and illustrative snapshots of the GUI taken by user) for physician's confirmation and for further diagnosis note input.

The IQQA-Liver Multimodality software supports a workflow based on automated registration for viewing and analyzing multi-phase volume datasets. The software automatically matches the spatial location of original DICOM 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 ducts 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 boundary editing, interactive definition of virtual resection plane, interactive adjustment of user specified margin size around the lesion, and regional analysis of such lesions with respect to size, shape, position, margin, enhancement pattern etc, thus providing information to support physician's assessment of lesion and treatment plans.

The software is designed for use by trained professionals, including physicians and technicians. Physicians make all final patient management decisions.

5. Safety and Effectiveness, comparison to predicate devices:
   The IQQA-Liver Multimodality software package has the same intended use as the predicate devices, and is substantially equivalent in performance. Any technological differences in the IQQA-Liver Multimodality software package and the predicate devices do not raise any new potential safety risks. In conclusion, the IQQA-Liver Multimodality software tool is substantially equivalent to the predicate devices.

6. Testing Information and Conclusion
   In all material respects, the IQQA-Liver Multimodality Software is substantially equivalent to the predicate systems. Testing was performed according to internal company procedures in recognition of the FDA guidance document for 510(k) software. 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. Additionally, to supplement the software validation for IQQA-Liver Multimodality Software, EDDA Technology has conducted software testing at two clinical sites. The purpose of the testing is to have physicians use the v2.0 software application to review multiphase CT and MR images of the liver, validate major functionalities provided by the system, and provide feedback along the line of the intended use of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 25, 2013

EDDA Technology, Inc.
% Daniel Kamm, PE
Regulatory Engineer, Submission Correspondent
5 Independence Way
PRINCETON NJ 08540

Re: K131498
Trade/Device Name: IQQA-Liver Multimodality Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 21, 2013
Received: May 30, 2013

Dear Mr. Kamm:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

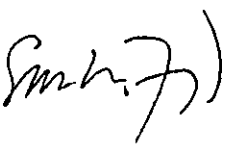
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131498

Device Name: IQQA-Liver Multimodality Software

Indications for Use:
IQQA-Liver Multimodality is a PC-based, self-contained, non-invasive image analysis software application for reviewing multiphase images derived from CT scanners and MR scanners. Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation and reporting of liver and physician-identified lesions.

The software supports a workflow based on automated image registration for viewing and analyzing multiphase volume datasets. It 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, interactive definition of virtual resection plane, and allows for regional volumetric analysis of such lesions in terms of size, position, margin and enhancement pattern, providing information for physician's evaluation and treatment planning.

The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.

Prescription Use _X_. 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 *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131498