K051127

JUN 3 - 2005

510(k) SUMMARY

KIKA Medical's KIKA Imaging Lab Viewer

Date Prepared:	April 14, 2005
Submitted by:	KIKA Medical, Inc 6 Beacon Street, Suite 220 Boston, MA 02108
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Device Trade Name:	KIKA Imaging Lab Viewer
Device Common Name:	Picture Archiving Communications System (PACS)
Regulation Number:	**892.2050**
Device Classification:	**Class II**
Name:	**Image Processing System**
Predicate Device:	**eFilm™ Workstation™ with Modules**
Predicate Device Manufacture:	**eFilm Medical, Inc.**
Predicate Device 510(k) Number:	**K020995**
Date Received:	
Decision Date :	
Decision:	**Substantially Equivalent**
Panel Code Device Reviewed by:	
Panel Code Device Classified by:	
Product Code:	**LLZ**
Regulation Number:	**892.2050**
Device Classification:	**Class II**

Device Description:

The KIKA Imaging Lab is a Web-based medical image and workflow management system that allows reviewing, manipulating, interpreting, archiving and interchanging medical multi-modality image in the DICOM

format. The functions of this workflow management system provide image viewing and manipulation in a diagnostic imaging setting. KIKA Imaging Lab Viewer is a secured web communication platform, to handle image management needs between all users of web clinical trials (investigators, experts, data managers etc.). The investigator may upload images from a CD source to a web based patient database, add annotations, adjusts display of images, scroll all the images of a DICOM series, and show cine playbacks.

Images are stored in a DICOM 3.0 compliant format using various different standard compression methods. Parameters and measurements are saved into a file attached to the image on the remote server. The original image is never altered.

The expert can then review images in a DICOM browser interface, retrieve images to local hard disc, do measurements (calibration, distance, area, angle) and display images in double view layout useful to compare images from different visits or series.

Indications for Use

KIKA Imaging Lab is intended to be used for diagnostic image management, archiving, annotation, acceptance, transfer, display, storage, image processing of diagnostic ultrasound, CD, MRI, and X-ray images, including manipulation, compression and quantification of images.

The KIKA Imaging Lab is typically used in web data sharing domains, especially in clinical trial management, post marketing surveillance, adverse event management, tele-expertise or telemedicine.

When interpreted by a trained physician, reviewed images can be used as an element for diagnosis.

Technological Characteristics

The KIKA Imaging Lab Viewer is a stand alone product or plug-in module that can be used on more than one platform and can be fully integrated into a host web server solution. Minimum requirements are the use of an Internet Web Browser and a broadband Internet connection with a Pentium-based or equivalent personal computer.

The system allows for digital image processing and measurement capability.

Testing

The KIKA Imaging Lab Viewer is tested according to the specifications that are documented in a Verification and Validation Test Description and Plan. Testing is part of KIKA Medical's software development process as described in KIKA Medical's Standard Operating Procedure 2.1.01SOP.en: Software Development Life Cycle. In all instances, the KIKA Imaging Lab Viewer functioned as intended and was all tests and validations observed as expected.

Substantial Equivalence

The KIKA Imaging Lab Viewer is as safe and effective as the UltrPro PACs and e-Film with Modules. The KIKA Imaging Lab Viewer has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between KIKA Imaging Lab, the UltrPro PACs and E-Film Workstation raise no new issues of safety or effectiveness. Performance Data demonstrate that the KIKA Imaging Lab Viewer is as safe and effective as the UltrPro PACs and E-Film Workstation. Thus, the KIKA Imaging Lab Viewer is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

John J. Talarico
c/o Howard M. Holstein, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

Re: K051127
Trade/Device Name: KIKA Imaging Lab Viewer
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 24, 2005
Received: May 3, 2005

Dear Mr. Talarico:

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 Statement

510(k) Number (if known): K051127

Device Name: KIKA Imaging Lab Viewer

Indications for Use:

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When interpreted by a trained physician, reviewed images can be used as an element for diagnosis.

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 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use __X__	AND/OR	Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051127