K071894

510(k) Summary of Safety and Effectiveness

Date Prepared

May 27, 2007

Submitter's Information

AUG 16 2007

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Contact Person

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Device

Trade Name:	Xebra DICOM Image Browser ™
Common Name:	Picture Archiving and Communications System
Classification Name:	PACS (per 21 CFR 892.2050), LLZ, Class II

Substantially Equivalent to both:

UniPACS Workstation (K023476) Universal PACS, Inc. 127 Albert Hart Drive Baton Rouge, LA 70803 www.unipacs.com	eFilm Workstation (K012211) eFilm Medical Inc. 500 University Ave, Suite 300 Toronto, Ontario Canada M5G 1V7 www.efilm.ca

Device Description

Xebra DICOM Image Browser ™ is one of the components of a Picture Archiving and Communications System (PACS). Xebra DICOM Image Browser ™ is a software application that provides image viewing and manipulation in a web browser. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM and or other proprietary formats. The device does not contact the patient, nor does it control any life sustaining devices.

Indications for Use

Xebra DICOM Image Browser ™ is a software application that is used for viewing medical images. The Xebra Image Viewer receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, and secondary capture devices, (scanners, imaging gateways or imaging sources). Images are stored, communicated, processed and displayed on the local disk of a workstation and/or across computer networks at distributed locations. Tasks that users may perform when viewing images include, but are not limited to: adjustment of window width and level; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips

of images. In addition, the Xebra Image Viewer can be integrated with an institution's existing HIS, RIS, EMR, or EHR for a fully integrated electronic patient record. Typical users of the Xebra Image Viewer are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. 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.

Technological Characteristics

The Xebra DICOM Image Browser ™ is a stand-alone software package which can be used on more than one hardware platform, as long as minimum hardware requirements are met and allows digital image processing and measurement capability. The Xebra Image Viewer does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed and/or printed.

Testing

Xebra DICOM Image Browser ™ has been tested according to the specifications that are documented in a Software Test Plan. Testing is an integral part of Hx Technologies' software development process as described in the company's Product Development Process.

Conclusion

The 510(k) pre-market notification for the Xebra DICOM Image Browser ™ contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

1. The Xebra Image Viewer has been and will continue to be manufactured according to the voluntary standards list in the Voluntary Standards section of the submission.
2. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 16 2007

Hx Technologies, Inc.
% Mr. Carl Alletto
Consultant
OTECH, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K071894
Trade/Device Name: Xebra DICOM Image Browser™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 4, 2007
Received: July 17, 2007

Dear Ms. Alletto:

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 Form)

510(k) Number:

Device Name:
Xebra DICOM Image Browser ™

Indications for Use:

Xebra DICOM Image Browser ™ is a software application that is used for viewing medical images. The Xebra Image Viewer receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, and secondary capture devices, (scanners, imaging gateways or imaging sources). Images are stored, communicated, processed and displayed on the local disk of a workstation and/or across computer networks at distributed locations. Tasks that users may perform when viewing images include, but are not limited to: adjustment of window width and level; image stacking; annotation and measurement of regions of interest; and inversion, rotation, and flips of images. In addition, the Xebra Image Viewer can be integrated with an institution's existing HIS, RIS, EMR, or EHR for a fully integrated electronic patient record. Typical users of the Xebra Image Viewer are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071894