

K081752

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
April 21, 2008

Submitter's Information: 21 CFR 807.92(a)(1)

AUG - 6 2008

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Edge PACS™
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807.92(a)(3)

Edge PACS™ is substantially equivalent to:

Manufacturer:	Voyager Imaging
Device Name:	Voyager PACS System
510(k) Number:	K062062
Product Code:	LLZ
Device Classification Name:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number:	Class II - 892.2050

Device Description: 21 CFR 807.92(a)(4)

Edge PACS, is a software device that consists of the Radion Workstation, Edge PACS Web Viewer, and Edge PACS Server and can be used for diagnostic viewing and manipulating of medical images. Digital images (including mammography and data from various sources (including CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or imaging sources) can be displayed, processed, stored and communicated across computer networks using this software. Edge PACS™ can be integrated with an institution's existing Hospital Information System (HIS) or Radiology Information System (RIS) providing access to reports for fully-integrated electronic patient records.

Edge PACS allows medical imaging centers to easily record patient details with study information along with their images and to prepare reports that can be distributed to the patient either in paper printout or through the Internet (email).

Moreover, it allows the user to retrieve images easily and to compare the images of the patient between different visits or to distribute the patient records in CD's. It also allows generating statistical data from the available details. Overall features include:

- Prevent unauthorized access of Patient Records
- Easy search of Patient details

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- Flexibility to design auto patient ID
- Report transmission by mail
- Cropping of live images
- Editing of AVI/cine loops
- Distribution of Reports and Images in CD
- Comparison of images between different visits of patient
- Tagging of significant images/cineloop for future references
- Generation of statistical data from available details

Indications for Use: 21 CFR 807 92(a)(5)

Edge PACS™ is a software device (server, web viewer, & workstation) used for diagnostic viewing and manipulating medical images. Digital images and data from various sources (including CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or imaging sources) can be displayed, processed, stored and communicated across computer networks using this software.

Edge PACS™ can be integrated with an institution's existing Hospital Information System (HIS) or Radiology Information System (RIS) providing access to reports for fully-integrated electronic patient records.

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: 21 CFR 807 92(a)(6)

Edge PACS™ is a software device that 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 printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for Edge PACS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ashva Technologies, Pvt., Ltd.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

AUG - 6 2008

Re: K081752

Trade/Device Name: Edge PACS™

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: July 23, 2008

Received: July 24, 2008

Dear Mr. Devine:

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 (PMA), 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.

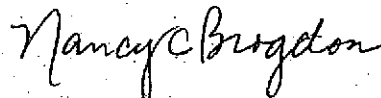
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) 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 Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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
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: K081752

Device Name:
Edge PACS™

Indications for Use:

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Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

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