K04 2647

CoActiv
MEDICAL BUSINESS SOLUTIONS

OCT 7 - 2004

CoActiv
EXAM-PACS™

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: August 28, 2004

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

Mr. Edward Heere, President & CEO
CoActiv, LLC
CoActiv Medical Business Solutions
900 Ethan Allen Highway,
Ridgefield, CT 06877

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

Trade Name:	Exam-PACS™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	System, Image Processing, Radiology
Regulation Number	892.2050
510(k) Number	K032533
Device Name	INTELEPACS™
Applicant	Intelerad Medical Systems Inc.
Product Code	LLZ
Decision Date	10/16/2003
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology

Device Description: 21 CFR 807 92(a)(4)

Exam-PACS™ is comprised of various software modules that can be configured to provide image capture, storage, distribution, enhancement, manipulation, and networking of medical images at distributed locations. In cases where DICOM images are not directly available to IntelePACS™, the system can acquire medical images using a DICOM image gateway, which generates DICOM-type files. For example, film digitizers obtain images from original film and convert them to meet DICOM standards and stored. Stored files are transmitted using a network and can be viewed or manipulated from imaging workstation.

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

Exam-PACS™ is a device that receives digital images (including mammograms) and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F units, computer & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and or across computer networks at distributed locations.
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. Typical users of this system are trained professionals, physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

Exam-PACS™ is medical device image software that is used with computer hardware in a picture archiving and communications system user environment. The device 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 Exam-PACS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

Exam-PACS™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

CoActive, LLC
% Mr. N. E. Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave., SE
GRAND RAPIDS MI 49548

Re: K042647
Trade/Device Name: EXAM-PACS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 28, 2004
Received: September 28, 2004

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 (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/dsma/dsmamain.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

510(k) Number: K042647

Device Name: EXAM-PACS™

Indications for Use:

Exam-PACS™ is a device that receives digital images (including mammograms) and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F units, computer & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and or across computer networks at distributed locations.

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.

Typical users of this system are trained professionals, physicians, nurses, and technicians.

Prescription Use ✓ 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 K042647