JAN 2 4 2007

510(k) Summary of Safety and Effectiveness K070080

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

Date Prepared: August 14, 2006

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

Intelerad Medical Systems Inc.
Anibal Jodorcovsky Executive Vice President, Quality Systems
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	IntelePACS™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing, Radiological

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

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K032533
Device Name	IntelePACS
Applicant	Intelerad Medical Systems Incorporated
Product Code	LLZ
Date Received	08/15/2003
Decision Date	10/16/2003
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K023460
Device Name	PACSPLUS
Applicant	MEDICAL STANDARD CO., LTD.
Product Code	LLZ
Date Received	10/15/2002
Decision Date	01/09/2003
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology

Device Classification Name	System, Image, Processing, Radiological
Regulation Number	892.2050
510(k) Number	K061672
Device Name	Synapse 3D MIP/MPR Image Visualization Software OBLIQUUS
Applicant	FUJIFILM Medical Systems USA, Inc.
Product Code	LLZ
Date Received	06/14/2006
Decision Date	06/29/2006
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology

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

IntelePACS™ is comprised of software modules that 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)
Technological Characteristics: 21 CFR 807 92(a)(6)

The device 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 IntelePACS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices.

IntelePACS™ system 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".

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K070080 Third Party Organization: Intertek Testing Services

Third Party's Primary Reviewer(s): Jay Y. Kogoma

ODE/OIVD Division: DRARD Branch/Team: RDB

Section 2 – 510(k) Decision

Third party recommendation: SE _x___ NSE ____ Other (specify): _____

ODE/OIVD final decision: SE _x___ NSE ____ Other (specify): _____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	X		
b. Extent of pre-submission consultation with ODE/OIVD division			
c. Organization and format of review documentation	X		
d. Determination of 510(k) administrative completeness (screening review)	X		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	X		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	X		
g. Rationale for conclusions and recommendation	X		
h. Use of guidance documents and standards	X		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	X		
j. Scope of reviewer expertise and use of consulting reviewers			
k. Other (specify):			

Comments (explanation of ratings/issues): _____

_____

_____

Section 4 – ODE/OIVD Assessor Information

Assessed by: Sunder Rajan Date: 1/22/07 Tel. No.: (240) 276 3968

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).

DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Intelerad Medical Systems, Inc.
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44067

JAN 24 2007

Re: K070080
Trade/Device Name: IntelePACS™ from Intelerad Medical Systems, Inc.
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 8, 2007
Received: January 9, 2007

Dear Mr. Lehtonen:

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

510(k) Number (if known): K070080

Device Name:

IntelePACS™ from Intelerad Medical Systems Inc.

Indications for Use:

IntelePACS™ is a device that receives digital images and data from various sources (such as, CT scanners, MR scanners, ultrasound systems, R/F units, computer and 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. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR).

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 __✓__ (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)

David A. Seymour

(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and Radiological Devices
510(k) Number K070080