

NOV - 8 2005

K 052545

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 30, 2005

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

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INFINITT CO., LTD
137-072 BITVILL 4~5F, 1327-33,
Seocho-Dong, Seocho-Gu, Seoul, Korea
Fax: 82-2-2194-1688

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

Trade Name:	Infinitt G3 PACS™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

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

510(k) Number	K042313
Regulation Number	892.2050
Device Name	INTEGRADWEB MPR/MIP
Applicant	DYNAMIC IMAGING INC.
Classification Product Code	<u>LLZ</u>
Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL

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

INFINITT G3 PACS is a web-based 3D-enabled DICOM viewing station running on Windows 2000/XP. It is adapted for, storing, processing routing and report generating. INFINITT G3 PACS fully supports the DICOM standard and such functions as advanced DICOM viewing, Hanging Protocol, 3D segmentation, various MPRs, fast 3D Volume Rendering, MIP, and Virtual Endoscopy.

INFINITT G3 PACS allows users to take full advantage of the radiographic images from various modalities in order to obtain invaluable mission critical diagnostic data and images. With INFINITT G3 PACS, users can have the same diagnostic environment of their own anywhere anytime because INFINITT G3 PACS is deployed through network and supports hanging protocol radically.

Indications for Use: 21 CFR 807.92(a)(5)

Infinitt G3 PACS is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, and displayed within the system or across computer networks at distributed locations. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography.

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, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

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

G3 PACS™ is a software product that handles digital medical images.

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 G3 PACS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

G3 PACS™ has been and 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".



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Infinit Co., LTD.
% Carl Alletto
Consultant
OTech Inc.
1600 Manchester Way
CORINTH TX 76210

Re.: K052545
Trade/Device Name: Infinit G3 PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 15, 2005
Received: September 15, 2005

Dear Mr. 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.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
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: K052545

Device Name:
Infinit G3 PACS™

Indications for Use:

Infinit G3 PACS is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, and displayed within the system or across computer networks at distributed locations. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography.

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

Jancy C. Bugdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052545