DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Infinitt Healthcare Co., Ltd.   October 27, 2017
C/O Carl Alletto
Regulatory Consultant
8317 Belew Dr.
McKinney TX 75071

Re: K172803
      Trade/Device Name: Infinitt PACS 7.0
      Regulation Number: 21 CFR 892.2050
      Regulation Name: Picture archiving and communications system
      Regulatory Class: II
      Product Code: LLZ
      Dated: September 9, 2017
      Received: September 26, 2017

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
    and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K172803

Device Name
Infinitt PACS 7.0™

Indications for Use *(Describe)*

Infinitt PACS 7.0™ is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations.

Only preprocessed 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 a monitor that meets technical specification identified by FDA.

Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)   ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:

September 8, 2017

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

Mr. Sang Wook Cho
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Infinitt PACS 7.0™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

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

Device Classification Name	system, image processing, radiological[22]
510(k) Number	K052545
Device Name	INFINITT G3 PACS
Applicant	INFINITT CO., LTD.
Regulation Number	892.2050[23]
Classification Product Code	LLZ[24]
Date Received	09/15/2005
Decision Date	11/08/2005
Decision	substantially equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
summary	summary[25]
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

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

Infinitt PACS 7.0™ device is PACS software capable of viewing and handling DICOM 3.x medical images. The System allows displaying of images and image studies that may not in the location as the modality. With its Web features, it is possible to review, modify, and approve studies located in a remote server.

INFINITT PACS is a software device that does not contact the patient, nor does it control any life sustaining devices. The software does not provide any diagnostic assistance to the physician. Any diagnostic determination or treatment is solely determined by a

physician and not the software. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

Infinitt PACS 7.0 is a web-based, 3D-enabled DICOM view station running on Windows 7/8.1/10. Infinitt PACS 7.0 is an integral component of INFINITT's complete INFINITT PACS/RIS solution. Infinitt PACS 7.0 fully supports DICOM standards and such functions as advanced DICOM viewing, Hanging Protocol, various 3D display such as MPR, Volume Rendering, MIP and fusion. Infinitt PACS 7.0 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 PACS 7.0, users can access their own diagnostic environment anywhere, anytime. This is made possible because Infinitt PACS 7.0 is deployed through a network and supports hanging protocol. Also, Infinitt PACS 7.0 uses JPEG 2000 features so that it takes less time to transfer images through a network.

Infinitt PACS 7.0 is based upon the INFINITT G3 PACS (predicate device). The features and functions of Infinitt PACS 7.0 have similar features and functions of G3 PACS with an updated operating system due to current advances in computer technology.

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

Infinitt PACS 7.0™, is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations.

Only preprocessed 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 a monitor that meets technical specification identified by FDA.

Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.

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

Infinitt PACS 7.0™ device is a software product that acquires, handles, displays and manages 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. The general features and functions of the device are:

510(k) Summary of Safety and Effectiveness

Category	Subject Device: INFINITT PACS 7.0	Predicate device: INFINITT G3 (K052545)	Explain why differences do not affect patient safety or effectiveness.
Overview			
General	• Same as predicate except for the operating system. ■ Runs on Microsoft Windows 7 / 8.1 / 10	• Runs on Microsoft Windows XP / Vista / 7 / 8.1 • Supports a combination of various types of monitors including VGA and high-resolution monitors • Integration-less synchronization of PACS and 3D functions • Automatically detects monitor resolution and magnification • Intuitively applies setting values • Links internal viewer to external HIS/RIS report system • Supports launching external programs with various parameter from specified exam information • Supports Direct CD/USB Burning and Media server backup • Supports Anonymize Direct CD/USB Burning and Media server • Stores all user settings in the database (Roaming user profile)	Differences: Subject Device does not run on Microsoft XP or Vista. The differences between the subject device and the predicate device is due to the advancement in computer OS technology since the time predicate device was cleared by FDA. Microsoft XP or Vista are no longer supported by Microsoft. The differences indicated, do not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the subject device.
Deploy	• Web-based deployment • Smart upgrade	• Web-based deployment • Smart upgrade	No differences
Compatibility - DICOM functions	• DICOM JPEG compression • DICOM JPEG2K compression • DICOM Security (TLS) • DICOM Multi-frame • DICOM Storage (SCU) • DICOM DIR - FSC, FSR, FSU • DICOM Query/Retrieve (SCU) • DICOM Grayscale Softcopy Presentation State (GSPS)	• DICOM JPEG compression • DICOM JPEG2K compression • DICOM Security (TLS) • DICOM Multi-frame • DICOM Storage (SCU) • DICOM DIR - FSC, FSR, FSU • DICOM Query/Retrieve (SCU) • DICOM Grayscale	No differences

	• DICOM Key Image Note • DICOM Multi-bytes character set • DICOM Print	Softcopy Presentation State (GSPS) • DICOM Key Image Note • DICOM Multi-bytes character set • DICOM Print	
Cyber security	• Supports secured network protocol • Supports auto log off • Supports audit logging • Restricting user behavior based on user roles and the institutional policies	• Supports secured network protocol • Supports auto log off • Supports audit logging • Restricting user behavior based on user roles and the institutional policies	No differences
Worklist			

Worklist	**General**
	• Supports various worklist mode
	  ■ Study list
	  ■ Favorite folder
	  ■ DICOM QR
	  ■ DICOM DIR
	  ■ Case
	  ■ Conference
	  ■ Technician worklist
	  ■ Embedded web browser
	  ■ Viewed history
	• Supports short cut button for the specific folders of each worklist mode (Quick access)
	• Support open the DICOM files directly (local open)
	Study list
	• Searches the exams that meet the multiple search conditions
	• Configurable fetching count for the exams.
	• Exam list displays various information describing the exams.
	• Add, delete, change position and sort of each information with header column control
	• Supports refreshing the exam list automatically by user configuration
		General
		• Supports various worklist mode
		  ■ Study list
		  ■ Favorite folder
		  ■ DICOM QR
		  ■ DICOM DIR
		  ■ Case
		• Support open the DICOM files directly (local open)
		Study list
		• Searches the exams that meet the multiple search conditions
		• Configurable fetching count for the exams.
		• Exam list displays various information describing the exams.
		• Add, delete, change position and sort of each information with header column control
		• Supports refreshing the exam list automatically by user configuration
		• Exports the list of the selected exams to text file or MS Excel compatible file (CSV)
		• Supports create/edit/delete search folders that contains the predefined search conditions
			Yes, there are differences. There is additional functionality in the subject device. The added features and functions of the subject device is described in labeling, so the User will be aware of the system functionality. The additional items do not change the Inductions for Use as compared to the predicate. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.

- Exports the list of the selected exams to text file or MS Excel compatible file (CSV)
- Supports create/edit/delete search folders that contains the predefined search conditions
- Caches the images to the local disk with On-Call function
- Exam list are configurable – font name, size, color
- Changes exam status using hospital specific terminology
- Launches the 3rd party application or web URL with selected exam information using External link
- Opens an exam or multiple exams in one click
- Opens only key images in the selected exam
- Scans documents and attaches to the selected exam
- Limit data access (Passcode Rule, Hiding rule, Folder Lock)
- Supports creating and view the comments of the study for private-use or sharing with specified user level.
- Assigns the priority of the study
- Assigns the referring doctor of the study
- Assigns the Radiologist (Read doctor) of the study
- Creates and shows technician note
- Creates and shows ER note
- Searches the historical exams of the selected exam
- Creates and shows the report of the selected exam

Favorite folder

- Caches the images to the local disk with On-Call function
- Exam list are configurable – font name, size, color
- Changes exam status using hospital specific terminology
- Launches the 3rd party application or web URL with selected exam information using External link
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- Creates and shows technician note
- Creates and shows ER note
- Searches the historical exams of the selected exam
- Creates and shows the report of the selected exam

Favorite folder

- Creates, edits and deletes the folder that are containing the

	• Creates, edits and deletes the folder that are containing the interesting exams. • Supports sharing with another user • Adds interesting exam to specified folder by mouse dragging from Study list or creating snapshot for favorite folder. • Also, supports common functions for exam in Study list **DICOM QR** • Supports the list of exams retrieved by DICOM query from DICOM compatible station. • Supports send the selected exam to other station. **DICOM DIR** • Supports the list of exams in DICOM DIR • Supports displaying the exam or sending it to other station. **Case** • Creates, edits and deletes the folder and case that are containing the interesting images • Supports sharing with another user **Conference** • Creates, Modifies and Deletes the folder of specified conference and make a schedule of it • Adds or deletes the exams for specified conference schedule • Opens conference exam with or without snapshot • Copies or moves the exams to next conference schedule • Create and view the note (minutes) of the conference **Technician worklist**	interesting exams. • Adds interesting exam to specified folder by mouse dragging from Study list. • Also, supports common functions for exam in Study list **DICOM QR** • Supports the list of exams retrieved by DICOM query from DICOM compatible station. • Supports send the selected exam to other station. **DICOM DIR** • Supports the list of exams in DICOM DIR • Supports displaying the exam or sending it to other station. **Case** • Creates, edits and deletes the folder and case that are containing the interesting images • Supports sharing with another user	

	• Searches order and exam List • Matches or un-matches the selected order and exams • Merges or un-merges the exam • Splits the series from the exam to new one • Modifies the information of the exam or the series **Embedded web browser** • Browses the web pages with predefined web URL **Dash Board** • Queries the number of exams that are met the specified condition • Shows the study list that are met the specified conditions **Notification** • Notices predefined schedules or events to PACS user.		
General Viewing	• Displays the DICOM images which are stored in PACS storage • Accesses historical exams and report : Timeline, Exam list • Supports image arrangement and manipulation using toolbar buttons, shortcut keys or screen shortcut • Support user-configurable mouse button action • Configures the initial settings for each specific modality • Supports job saving • Export or convert the displayed images as DICOM or general image formats	• Displays the DICOM images which are stored in PACS storage • Accesses historical exams and report : Exam list • Supports image arrangement and manipulation using toolbar buttons or shortcut keys • Support user-configurable mouse button action • Configures the initial settings for each specific modality • Supports job saving • Export or convert the displayed images as DICOM or general image formats	Yes, there are differences. There is additional functionality in the subject device. The added features and functions of the subject device is described in labeling, so the User will be aware of the system functionality. The additional items do not change the Inductions for Use as compared to the predicate. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Toolbar	**Common tools** • Select • Pan	**Common tools** • Select • Pan	Yes, there is an added "Findings List" feature in the subject device.

	● Zoom ● Windowing ● Magnification ● Fit ● Capture ● Reset ● Print: Report / Film ● 3D cursor ● Exam Refresh ● Dictation (play, record) ● Set as tape dictated ● Hide demographic information ● Save snapshot ● Apply previous / next HP sequence ● Specific zoom: 100%, 1:1 Display (Monitor screen) **Annotation / Measurement tools** **Image Display** **3D Tools** **Etc tools** ● Display DICOM information tool ● Monitor cine controller ● Save ● Call case folder ● External link ● About	● Zoom ● Windowing ● Magnification ● Fit ● Capture ● Reset ● Print: Report / Film ● 3D cursor ● Exam Refresh ● Dictation (play, record) ● Set as tape dictated ● Hide demographic information ● Save snapshot ● Apply previous / next HP ● Specific zoom: 100%, 1:1 Display (Monitor screen) **Annotation / Measurement tools** **Image Display** **3D Tools** **Etc tools** ● Display DICOM information tool ● Monitor cine controller ● Save ● Call case folder ● External link ● About	The added feature is described in labeling, so the User will be aware of the system functionality. The additional item does not change the Inductions for Use as compared to the predicate. The difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Thumbnail	● Thumbnail display: series, image ● Displays series number and how many images are in specific series ● Displays an icon about the property of the series: Only one image in series, Multiple images in series, Multi-frame image in series ● Supports opening the series or image by drag and drop the thumbnail or click it	● Thumbnail display: series, image ● Displays series number and how many images are in specific series ● Supports opening the series or image by drag and drop the thumbnail or click it	Yes, there is a difference in that the subject device displays an icon about the property of the series: Only one image in series, Multiple images in series, Multi-frame image in series. The added feature is described in labeling, so the User will be aware of the system functionality. The additional item does not change the Inductions for Use as compared to the predicate. The difference does not

			raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Layout	• Supports monitor merge • Supports displaying multiple exams in a monitor by image set layout • Supports displaying multiple series or images in the image set by cell layout	• Supports monitor merge • Supports displaying multiple exams in a monitor by image set layout • Supports displaying multiple series or images in the image set by cell layout	No differences
Visual Timeline	• Displays the information of the patients that are opened • Displays the list of all historical exams or relevant exams only for specific patient • Displays the report text of the specific historical exam • Displays the series thumbnails of the specific historical exam • Displays jobs and snapshots in this area when creating it. (Job container)	• (N/A)	Yes, differences. This is a new feature that is not in the predicate device. The added features and functions of the subject device is described in labeling, so the User will be aware of the system functionality. The additional items do not change the Inductions for Use as compared to the predicate. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Advanced Hanging Protocol	• Applies the user configurable hanging protocol for each type of exam when it is opened • Support tools for managing user hanging protocols: Create / Copy / Export / Import / Copy from another user / Delete / Search • Support user configuration for below settings in a hanging protocol • Support multiple layout sequences in a hanging protocol (hanging protocol layout group)	• Applies the user configurable hanging protocol for each type of exam when it is opened • Support tools for managing user hanging protocols: Create / Copy / Export / Import / Copy from another user / Delete / Search • Support user configuration for below settings in a hanging protocol	Yes, there is a difference between the subject and predicate devices. The subject support multiple layout sequences in a hanging protocol (hanging protocol layout group). This is a new feature that is not in the predicate device. The added features and functions of the subject device is described in labeling, so the User will be aware of the system functionality. The additional items do

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			not change the Inductions for Use as compared to the predicate. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Image Display			
Common	• Support display mode: Stack / Image / Preset (VR / MPR / MIP / Web URL / Report) • Maximize and restore displayed image • Support crosslink among the series in same study • Support linked scrolling among the exams, even for difference exams • Support linked scrolling by manual-selection • Support monitor cine control for stack mode • Sets as key image • Rearranges the images by image information (Sort): image time/number/echo time/image position • Supports sequence display (Position/Time) for specific data	• Support display mode: Series / Image / Preset (VR / MPR / MIP / Endo / FMX) • Maximize and restore displayed image • Support crosslink among the series in same study • Support linked scrolling among the exams, even for difference exams • Support linked scrolling by manual-selection • Support monitor cine control for series mode • Sets as key image • Rearranges the images by image information (Sort): image time/number/echo time/image position • Supports sequence display (Position/Time) for specific data	No differences
Advanced Display			
Fusion	• Adjustable blending rate • Separated windowing for each fusion data • Screen capture for further use	• Manually adjusted registration • Adjustable blending rate in MIP/MPR fusion • Separated windowing for each fusion data	No differences
Mammo Display	• Mammo CAD interface: R2 • Mammo CAD interface : i-CAD SR • Mammo Hanging Protocol Loop Sequence • Mirror function: Zoom,	• Mammo CAD interface: R2 • Mammo CAD interface : i-CAD SR • Mammo Loop Sequence • Mirror function: Zoom,	No differences

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	Magnification, Pan, B/W Invert ● Quadrant Zoom ● Clear Filter ● Custom View Layout ● Auto breast fit display ● Breast Tomosynthesis view mode ● Controlled with INFINITT Mammo Keypad (option)	Magnification, Pan, B/W Invert ● Quadrant Zoom ● Clear Filter ● Custom View Layout ● Auto breast fit display ● Breast Tomosynthesis view mode ● Controlled with INFINITT Mammo Keypad (option)	
3D Display			
Image display - Common	**Volume Rendering** ● OTF windowing: See below in more detail ● Interactive 3D rendering reflecting the change of OTF ● VOI display (slab rendering): See below in more detail ● Batch rendering ● Orientation cube display ● Orientation preset ● Bounding box display ● Synchronize VR with MIP **MPR** ● Supports classic reformation planes: Axial, Sagittal, Coronal and Oblique plane ● Supports image scroll using mouse drag on images ● Various crosshair shape: Show/Hide, Hollow, Small size ● Double oblique MPR ● Curved MPR ● Rotate reformation plane ● Batch MPR with cine support ● Slab MPR: Raysum, MIP, MinIP	**Volume Rendering** ● OTF windowing: See below in more detail ● Interactive 3D rendering reflecting the change of OTF ● VOI display (slab rendering): See below in more detail ● Batch rendering ● Orientation cube display ● Orientation preset ● Bounding box display ● Synchronize VR with MIP **MPR** ● Supports classic reformation planes: Axial, Sagittal, Coronal and Oblique plane ● Supports image scroll using mouse drag on images ● Various crosshair shape: Show/Hide, Hollow, Small size ● Double oblique MPR ● Curved MPR ● Rotate reformation plane ● Batch MPR with cine support ● Slab MPR: Raysum, MIP, MinIP	No differences
Output			
Print	**General** ● Prints the images and report with paper or DICOM printer ● Sends the images and	**General** ● Prints the images and report with paper or DICOM printer ● Sends the images and	No Differences

	report to DICOM station • Export the images and report to MS PowerPoint • Various layout adjustment • Report print with output template which is configurable for specific hospital • Selects images for printing • Prints images with or without patient information, annotations and scale bar	report to DICOM station • Export the images and report to MS PowerPoint • Various layout adjustment • Report print with output template which is configurable for specific hospital • Selects images for printing • Prints images with or without patient information, annotations and scale bar	
Report	**General** • Supports Built-in report module • Support displaying the information of the reading exams • Supports Reading workflow • Supports temporally suspending the report • Supports merging the reports of multiple unread exams of a patient • Supports printing the text report with template **Dictation** • Stores the voice with MP3 voice file format and updates the exam status for it. • Interface with Philips Speech Mike controller **Text Report** • Displays the reading history who and when creates, updates and approves the report • Displays a report of historical exams of the patient and copy the text from it • Displays a predefined report template and copy the text from it (Standard report) • Supports user-defined standard report	**General** • Supports Built-in report module • Support displaying the information of the reading exams • Supports Reading workflow • Supports temporally suspending the report • Supports merging the reports of multiple unread exams of a patient • Supports printing the text report with template **Dictation** • Stores the voice with MP3 voice file format and updates the exam status for it. • Interface with Philips Speech Mike controller **Text Report** • Displays the reading history who and when creates, updates and approves the report • Displays a report of historical exams of the patient and copy the text from it • Displays a predefined report template and copy the text from it (Standard report)	No Differences

	Voice Recognition ● Interface with INFINITT Result (Optional) ● Interface with 3rd Party VR system (Optional)	● Supports user-defined standard report **Voice Recognition** ● Interface with INFINITT Result (Optional) ● Interface with 3rd Party VR system (Optional)	

Testing

> The complete system configuration has been tested at the factory and the device has passed all in-house pre-determined testing criteria without significant failures. The data presented in the submission demonstrates that Infinitt PACS 7.0™ performs as required according to the functional requirements specified in the Software Requirements Specification and the User Manual with no errors that had an impact on safety or efficacy.

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

> The 510 (k) Pre-Market Notification for Infinitt PACS 7.0™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. Infinitt PACS 7.0™ 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 "Moderate".