K051586

AUG 4 - 2005

SECTION 3

SECTION 510(k) SUMMARY

The following information was completed on May 31, 2005. It is submitted in compliance with the provisions of 21 CFR 807.92:

807.92 (a)(1)

(a) Submitter's Name:

Kenei Co., Ltd
5-13-9 Higashi Ueno
Taito-ku
Tokyo, Japan 110-0005

(b) Contact Person:

Jennifer Li
6899 Churchill Road
McLean, Virginia 22102
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Email: jennli@viewsend.com

807.92 (a)(2)

(a) Device Name:

VIEWSEND Medical System

(b) Trade/Proprietary/Common Name:

VIEWSEND Medical
VIEWSEND Medical 7 (Plus and Lite)
VIEWSEND Medical 7.5 (Plus and Lite)
VIEWSEND Telemed DICOM Server
VIEWSEND RAD Plus and Lite; Client Station, Viewing Station

(c) Classification Name: System, Image Processing, Radiological

807.92 (a)(3) Identification of Legally Marketed Device to Which Kenei Claims Equivalence

The VIEWSEND Medical System is equivalent to a legally marketed predicate system; specifically, VIEWSEND Medical Products marketed by KLT Telecom, Inc. ("KLT") pursuant to an authorization issued by CDRH on October 25, 1996 (K-962225).

807.92 (a)(4) Identification of Device That is Subject of this Premarket Notification Submission

The VIEWSEND Medical System is a modular software program providing telemedicine, teleradiology, and videoconferencing capabilities. The system may also utilize some or all of the following components:

(1) **DICOM**

- Image file format complies with industry standard DICOM 3.0 protocols; and

- Query, retrieve, send, receive, DICOM Direct, and DICOM print all conform with DICOM 3.0 protocols.

(2) **Zydacron**

- **Features:**

User Interface:

Full feature video teleconferencing application

Audio:

Standards: G.711, G.722, and G.728
One line level input/output
Balanced microphone input
Amplified speaker output
RJ-11 jack to connect to standard POTS telephone or fax machine
Hook and DTMF detection for dialing
Automatic gain control
Full duplex echo cancellation
Noise suppression

Video:

Standards: H.261
Two video inputs S-video or composite
NTSC or PAL
Analog VGA input from VGA board, no feature connector
VGA output
CIF/QIF resolution
PIP window

Data:

Built in file transfer and messaging commands
Serial port emulation supports popular groupware applications
Optional network emulation supports TCP/IP applications

Comm Board Options - Signaling Standards: H.320, H.221, H.230, H.242, H.243

ISDN-BRI/PRI Ethernet Iso-Ethernet
V.35 Interface
MVIP compatible boards

Customization Options:

ZDK for custom application development
Installation kits for custom install disk and manuals
Call control development kit for integrating new communication systems
Host comm. development kit for integrating host bus based communication system

(3) **Canon Communication Camera**

- **Features:**

Video Signal:	TCC video signal
Image Sensor:	1/3-inch CCD
Total # of Pixels:	410,000 pixels
Synchronization:	Internal
Horizontal Resolution:	450 TV lines
Vertical Resolution:	350 TV lines
S/N ratio:	43dB
Scanning Method:	2 : 1 interlace
Pan Mechanism:	Rotation angle: RT-LT (+ or -) 50 degress. Rotation speed: Maximum of 38 degress/second
Tilt Mechanism:	Rotation angle: RT-LT (+ or -) 20 degress. Rotation speed: Maximum of 35 degress/second
Input Terminal:	MIC IN mini-jack x 1 (input impedance approx. 5k ohms)
Output Terminal:	Audio Out: pin jack x 1 (O/P impedance approx. 1k ohms) Video Out: pin jack x 1 (O/P impedance approx. 75 ohms) S Video Out: S-video jack x 1 (O/P impedance approx. 75 ohms)
Control Terminal:	RS-232C: Mini DIN x 1 Communication Standards: RS-232C level Data Bit: 8 bit Parity: None Stop Bit: 2 bit Handshake: RTS/CTS control
Focusing:	Auto/Manual
Iris Adjustment:	Auto iris servo system
Lens:	f/1/8 -2.6 8x power zoom 6-48 mm focal length
White Balance:	TTL system, full auto white balance
Power Supply/Other:	Pwr Source: Commercial power supply 120V AC, 60Hz Pwr. Consumption: Max. 17W (AC adapter included) Weight: Approx. 2.2 lbs. (1kg) Dimensions: 4 15/16 x 6 1/4 x4 1/16" (125 x 158 x 103 mm) Temp. Hum.: 41 F-95 F (5C-35C), 20% -85

	Angle:	(+ or -) 30 degrees from a hoz. position
Wireless Controller:	Type :	WL-V1
	System:	Infrared pulse system
	Pwr. Supply:	DC 3V (Two R6/AA batteries)
	Dimensions:	1 13/16 x 6 11/16 x 11/16 inches (45 x 169.5 x 19 mm)
AC adapter:	Type:	PA -V6
	Input Level:	120 V AC 60Hx 27VA
	Output Level:	12 V DC 1.5 A (max)
	Polarity:	Outside (-)
	Dimensions:	2 1/4 x 3 15/16 x 1 7/8 inches (58 x 100 x 49 mm)
	Weight:	Approx. 1.4lbs (690g)

(4) **COHERENT Call Port Display Audio Conferencing System**

• **FEATURES:**

Frequency Response (1 kHz reference)

Transmit:	200 Hz to 3.4 kHz (+ or - 1dB)
Receive:	200 Hz to 3.4 kHz (+ or - 1dB)

Harmonic Distortion:	Microphone to audio output:	0.5% maximum
	Audio Input to Loudspeaker:	0.1% maximum at 1 watt output (1kHz)

Audio Power: 3 watts peak to loudspeaker

Dynamic Range: 70 dB minimum

Echo Control:

Acoustic Tail Circuit Delay:	68 mS
Center Clipper (NLP):	Adaptive

AERL Enhancement: 65 dB min. with NLP enabled
Continuously adaptive echo cancellation during normal speech

Input/Output Impedance:	Input:	Headphone 10 k ohms Line 50 k ohms
	Output:	Microphone 100 ohms Line 50 ohms
Normal Levels:	Input:	Headphone -25 dBm Line -33 dBm
	Output:	Microphone -58 dBm Line -27 dBm
Power Requirements:		Power is derived using the 120 VAC power supply included with the Call Port

(5) **Canon RE-650 MKH Video Visualizer Document Camera**

• **FEATURES:**

Video Signal:	Conforms to NTSC color Format
Pick-up Element:	1/3 - inch CCD
Total # of Pixels:	410,000 (811H X 508V)
Synchronization:	Internal
Horizontal Resolution:	450 TV Line
Vertical Resolution:	350 TV Lines
S/N:	46dB
White Balance:	Automatically adjusted
Negative/ Positive Conversion:	Possible
Input Source:	Camera head and two (2) other sources

Input/Output Terminals:

Video In	Pin jack x 2
Video Out	Pin jack x 2
S-Video Out	S-Video jack x 1
Audio In	Pin jack x 2
Audio Out	Pin jack x 2
Mic In	Mini-jack x 1
AC outlet	120VAC, 5A max.

External Input Microphone Input Impedance: 450 to 1,200 ohms (mini jack)

Lens (for Rear Position) Zoom Lens, 5.2 62.4 mm f/1.8 - 2.8 (8 - group 10 - group)

Document table Lens: 500 mm close-up lens (1 - group 2 - element)

Ranges: 16 - 7/32" x 12 - 13/32" to 1 - 13/32" x 1 - 1/16"
(412 x 315 mm to 35.5 x 27mm) NORMAL position
12 -5/8' x 9- 29/64" to 1 -13/64" x 7/8"
(320 x 240 mm to 30.5 x 22.5 mm) in CLOSE UP position

Zoom: Power Zoom

Focusing: Auto/Manual

Iris Adjustment: Automatically adjusted (fine-adjustable)

Zoom Position Memory:	Zoom position setting saved when power turned off
Electronic Shutter:	Two (2) settings, 1/60 and 1/100
Camera Head Positions:	NORMAL, CLOSE-UP, REAR
Illumination:	6W fluorescent lamp (FL6W) x 2, angle-adjustable
Outside Dimension:	26 - 1/16" (W) x 26- 3/4: (H) x 21 - 3/4" (D) (662 (W) x 680 (H) x 553 (D) mm)
Stored Dimension:	15 -3/4" (W) x 8 -1/16" (H) x 21 -3/4" (D) (400 (W) x 205 (H) x 553 (D) mm)
Weight:	Approx. 22lbs (10kg)
Power Source:	120VAC 60Hz
Power Consumption:	25 W

807.92 (a)(5) Intended Uses and Indications.

See **Section 2** above

807.92 (a) (6) Technological Characteristics

(i) Introduction

The VIEWSEND Medical System is a modular software program providing telemedicine, teleradiology, and videoconferencing capabilities. The software can be installed and configured to provide one or more of these capabilities as shown in Table 3-1.

VIEWSEND Medical Version	Telemedicine	Videoconferencing	Collaboration	DICOM	Communications	Viewer	Storage	Customizable DB	Stand Alone	Client/Server	Web-based	Compression	Security
Plus/Lite	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓
RAD Workstation			✓	✓	✓	✓				✓	✓	✓	✓
RAD Viewer				✓	✓	✓			✓	✓	✓	✓	✓
MDOffice	✓	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓
RIX	✓			✓	✓	✓			✓			✓	✓
Web-RIX	✓			✓	✓	✓					✓	✓	✓
Server				✓	✓		✓	✓		✓	✓	✓	✓

Table 3-1 **Version names for common VIEWSEND Medical installation options**

(ii) System Specifications

The following minimum hardware and software components have been qualified for use with the VIEWSEND Medical System (not all items listed are required for install or use):

(b) **Operating Systems**

Windows 2000 Workstation
Window XP Professional (Service Pack 2)
Windows NetMeeting 2.1, 3.x

(c) **Hardware**

Pentium IV – 1.8 GHz processor
512 MB Ram
80 GB Hard disk drive
Zydacron Z350, Z360 Video Codec
VCON Escort, Cruiser Video Codec
ISDN Telecommunication Board
Video capture card
56K Modem
Network Interface Card
Mouse/Keyboard
Video Camera
Mic & Speaker combination

(d)

(e) **Displays**

The medical professional will follow their current industry standard recommendations for clinical and diagnostic display – currently minimum 1.5K x 2.0K resolution for diagnostic purposes.

Clinical display - 17" SVGA monitor at 1024x768 screen resolution

Diagnostic Display - Medical Grade Grayscale monitor(s) at 1.5 x 2.0k resolution with medical grade graphics board

(f) **Compression**

The VIEWSEND Medical System complies with the following standard adopted by the American College of Radiology (ACR Standard for Digital Image Data Management, 1998 Res.15):

"Data compression may be performed to facilitate transmission and storage. Several methods, including both reversible and irreversible techniques, may be used under the direction of a qualified physician, with no reduction in clinical diagnostic image quality. The types and ratios of compression used for different imaging studies transmitted and stored by the system should be selected and periodically reviewed by the responsible physician to ensure appropriate clinical image quality."

Diagnostic wet reads can be made according to radiologist industry standard recommendations. Currently radiologists require medical grade grayscale monitors and uncompressed image formats. JPEG or JPEG2000 compression can be applied and used according to ACR's guidelines - at the reader's discretion. VIEWSEND Medical is compliant with these requirements.

Lossy compression will be apparent to the reader when using the VIEWSEND Medical System. As shown in Figure 3-1 below, the compression applied to an image can be displayed. In this way, both the compression mechanism and the ratio can be seen.

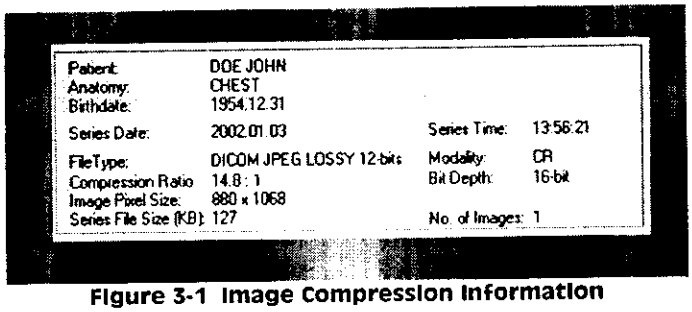

Figure 3-1 Image Compression Information

(d) Checklist

The Section 510(k) Summary Checklist follows immediately after this Section 3.

807.92 (a)(6) Incremental Technological Improvements to Predicate Device

The VIEWSEND Medical System includes incremental technological features which have been added to the predicate device as indicated in Section 1, 807.87(g) and Chart 1-1 above

807.92 (d) Other Information – Safety and Effectiveness.

The following information will provide certification as to the subject of safety and effectiveness analysis.

The VIEWSEND Medical System is comprised of modular software that provides telemedicine, teleradiology and videoconferencing capabilities. This system is described in detail in Section 1 above. Further, the software has been evaluated in accordance with CDRH's "Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review". Based on this review, a low level of concern was assigned to the software. Provided below is a discussion of the software's development process.

VIEWSEND Medical was developed based on an off-the-shelf medical software product known as Osiris 2.5. The Osiris 2.5, a Windows-based radiology package, was developed by University of Geneva Medical Center as part of its PACS system. The Osiris software is built upon C++ object oriented methodology with well-defined interface for each software module. C++ exception handling is built in to minimize system malfunction and to provide a graceful system exit without data loss. All DICOM routines are from Merge Technologies. JPEG 2000 routines are from Pegasus.

VIEWSEND Medical provides image transmission and storage. TCP/IP protocol is used to guarantee reliable image transmissions among VIEWSEND Medical workstations in local and wide area networks. Zmodem and FTP protocols are used as well for direct modem-to-modem connections.

As established with the unmodified device, and as stated as the intended use of both the unmodified and the modified device, VIEWSEND Medical System software does NOT:

- Threaten the patient's life
- Cause irreversible illness or injury
- Directly control delivery of energy
- Administration of parental drugs
- Perform life-sustaining functions
- Provide alarms for life threatening conditions
- Provide a diagnosis recommendation or statement (such as an expert system)

In addition, it has always been maintained, and supported by ACR, that healthcare professionals shall exercise their own judgment when using the displayed information for diagnosis.

Standard software development policy/procedures were followed by Kenei's predecessor in order to provide quality assurance. Test plans were developed in the process and used for testing, verification and validation tasks. Testing results demonstrated that the software functional requirements were met, and that the software specifications were fulfilled.

The following matrix is provided as a summary to demonstrate that Kenei's predecessor has sufficiently analyzed the safety of each incremental software revision, established the basis for appropriate development, and implemented safety/performance requirements.

	Incremental Software Revisions	A	B	C	D	E	F	G	Comment	Hazard Level of Concern
	User Interface Updates									
1	Added Patient Work List with read/unread status indicators	N	N	N	N	Y	Y	N		Minor
2	Added user preferences tool	N	N	N	N	Y	Y	N		Minor
3	Added floating toolbar	N	N	N	N	Y	Y	N		Minor
4	Single address book is used for systems configured with both H.320 and H.323 standards	N	N	Y	N	Y	Y	N		Minor
5	Revised the toolbar to flatbar standard with support for various screen resolutions	N	N	N	N	Y	Y	Y		Minor
6	Added window width/level presets	N	N	Y	N	Y	Y	Y		Minor
7	Added Japanese localization	N	N	N	N	Y	Y	Y	Localization completed by Akira Tanaka, Melon System, Inc., Japan	Minor

	Incremental Software Revisions	A	B	C	D	E	F	G	Comment	Hazard Level of Concern
	User Interface Updates									
8	Viewer now follows radiology workflow more closely	N	N	N	N	Y	Y	Y		Minor
	Feature Additions									
9	Enable or disable the automatic forwarding capability of patient information received by VIEWSEND Medical station to another DICOM station	N	N	N	N	Y	Y	N		Minor
10	Enable or disable the lossless compression capability for each transfer item in the transfer list queue	N	N	N	N	Y	Y	Y		Minor
11	Enable or disable the FTP transfer capability before each consultation session. If FTP transfer is enabled before the connection process occurs, VIEWSEND Medical station will attempt to establish an FTP link to be used for all the file transfer activities during the subsequent consultation session	N	N	N	N	Y	Y	Y		Minor
12	Added VIEWSEND log file to detail the actions performed during use	N	N	N	N	Y	Y	N		Minor
13	Added DICOM interface to include query, retrieve, send, receive, print, and DICOM Dir	N	N	N	N	Y	Y	Y	DICOM toolkit provided by Merge for all data transfer	Minor
14	Added store and forward e-mail send capability	N	N	N	N	Y	Y	Y		Minor
15	Added dual video source switching	N	N	N	N	Y	Y	N		Minor
16	Added capability of saving video captured images and scan images into DICOM secondary capture image format	N	N	N	Y*	Y	Y	N	* Used same algorithm as with film images in the unmodified device	Minor

	Incremental Software Revisions	A	B	C	D	E	F	G	Comment	Hazard Level of Concern
17	Added the capability to automatically forward study information received from DICOM modalities using DICOM Send. In addition, study information received from another VIEWSEND Medical station during collaboration can be automatically forwarded using DICOM Send	N	N	N	N	Y	Y	N		Minor
18	Application sharing is now available for VIEWSEND Medical systems configured with H.320 standard-	N	N	N	N	Y	Y	Y		Minor
	Software/Hardware Support									
19	VIEWSEND is now a 32-bit application	N	N	N	N	Y	Y	N	NT/Win2K 32-bit support provided by C++ development code	Minor
20	Added industry standard JPEG2000 compression option - ISO International Standard, IS 15444 Part 1. The 'Joint' in Joint Photographic Experts Group refers to the link with ITU-T, and IS 15444-1 will also be an ITU-T Recommendation, T.800	N	N	N	Y*	Y	Y	Y	* Used ISO international standard in toolkit from Pegasus	Moderate
21	Added capability to print overlays and image to laser printer	N	N	N	N	Y	Y	N		Minor
22	Added industry standard 128-bit encryption option. The encryption algorithm is based on the standard Rijndael algorithm, as specified in the Advanced Encryption Standard (AES) developed by the U.S. National Institute of Standards and Technology (NIST). The AES is a block cypher that uses long keys (128-, 192-, 256-bit) for data encryption	N	N	N	Y*	Y	Y	N	* Used industry standard 128-bit algorithm provided by Microsoft (MS)	Minor
23	Added support for Zydacron 350, 360 and VCON escort, cruiser, and VIGO boards	N	N	N	N	Y	Y	Y		Minor

	Incremental Software Revisions	A	B	C	D	E	F	G	Comment	Hazard Level of Concern
24	Added support for Cannon VCC4 camera	N	N	N	N	Y	Y	N		Minor
25	Added MS SQL client/server support	N	N	N	N	Y	Y	Y		Minor
26	Added PowerPoint Presentation support in videoconferencing	N	N	N	N	Y	Y	Y		Minor
27	Added MPEG4 video format support	N	N	N	N	Y	Y	Y		Minor

A – Could the failure or latent design flaw in this revision immediately threaten the patient's life under plausible conditions?

B – Could the failure or latent design flaw in this revision directly cause irreversible illness or permanent injury under plausible conditions?

C – Does the failure or latent design flaw in this revision consolidate or obscure information or data that is available to the user in the unmodified device?

D – Could software errors in this revision potentially lead to diagnostic or monitoring information to be missed or inaccurate?

E – Were software specifications, requirements, and design set forth for this revision?

F – Was this revision verified and validated through KLT testing criteria?

G – Was regression testing required to maintain this revision?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2005

Kenei, Co., Ltd.
% Ms. Jennifer Li
United States Agent
Vanguard Solutions Technology, LLC
6899 Churchill Road
MCLEAN VA 22101

Re: K051586
Trade/Device Name: VIEWSEND Medical System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 2, 2005
Received: June 16, 2005

Dear Ms. Li:

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

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): K051586

Device Name: VIEWSEND Medical System

Indications For Use:

The indications for use of the VIEWSEND Medical System, as described in its labeling, are the same as the previously cleared devices marketed and distributed by KLT telecom, Inc. (K-962225). The VIEWSEND Medical System has the same intended use as the originally cleared device.

When installed on an appropriate PC-based platform, the VIEWSEND Medical System is intended to provide the medical professional with the capability to compare, manipulate, annotate, collaborate, and/or transmit medical images in order to render a diagnosis. Digital image storage in system RAM and hard drive standard is with lossless compression or without data compression. Options include teleradiology, telemedicine, videoconferencing, communications, viewer, customizable database, DICOM 3.0, stand-alone or client/server or web-based, compression, and/or security.

Communications between systems can be performed over wireless/wired LAN, ISDN, T1, ATM, satellite, and/or plain old telephone system (POTS). The DICOM 3.0 option allows for query, retrieve, send, receive, print, or DICOM Dir actions with DICOM 3.0 compliant modalities or servers.

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 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K051586

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051586