K05 1521

510(k) Summary

as required by 807.92

JUN 28 2005

1. Company Identification

KONICA MINOLTA MEDICAL & GRAPHIC, INC.
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2. Official Correspondent

Koji Kubo(Mr.)
Department TS Advanced Technology Division R & D Center

3. Date of Submission

June 6, 2005

4. Device Trade name, Common Name

REGIUS RS-1000, Medical Image Processing Workstation

5. Classification

Class II, 90-LLZ, 21CFR 892.2050, Picture archiving and communications system

6. Intended Use

Receive and process electronic images of patients

7. Applicable mandatory and voluntary standards

REGIUS RS-1000 complies with the following mandatory and voluntary standards:

- Information Technology Equipment Part 1: General Requirements for Safety UL Standard 60950
- Information Technology Equipment, Radio Disturbance (Emissions) Characteristics – Limits and Methods of Measurement, IEC/CISPR 22 (EN55022)
- Information Technology Equipment, Immunity Characteristics – Limits and Methods of Measurement, IEC/CISPR 24 (EN55024)
- DICOM (Digital Imaging and Communications in Medicine) Developed by the American College of Radiology and the National Electrical Manufacturers Association

8. Description of Device

REGIUS RS-1000 is Konica Minolta Image Quality Control Terminal.
REGIUS RS-1000 has the hard disk for storing the digital images.
REGIUS RS-1000 consists of a workstation computer with keyboard and mouse for input, LAN interface for communication, color or monochrome CRT or LCD for displaying.
REGIUS RS-1000 processes the images received from a single or multiple CR (Computed Radiography) devices with the auto gradation processing function, etc. and outputs them to one or multiples storage devices, such as the host computer or a film printer.

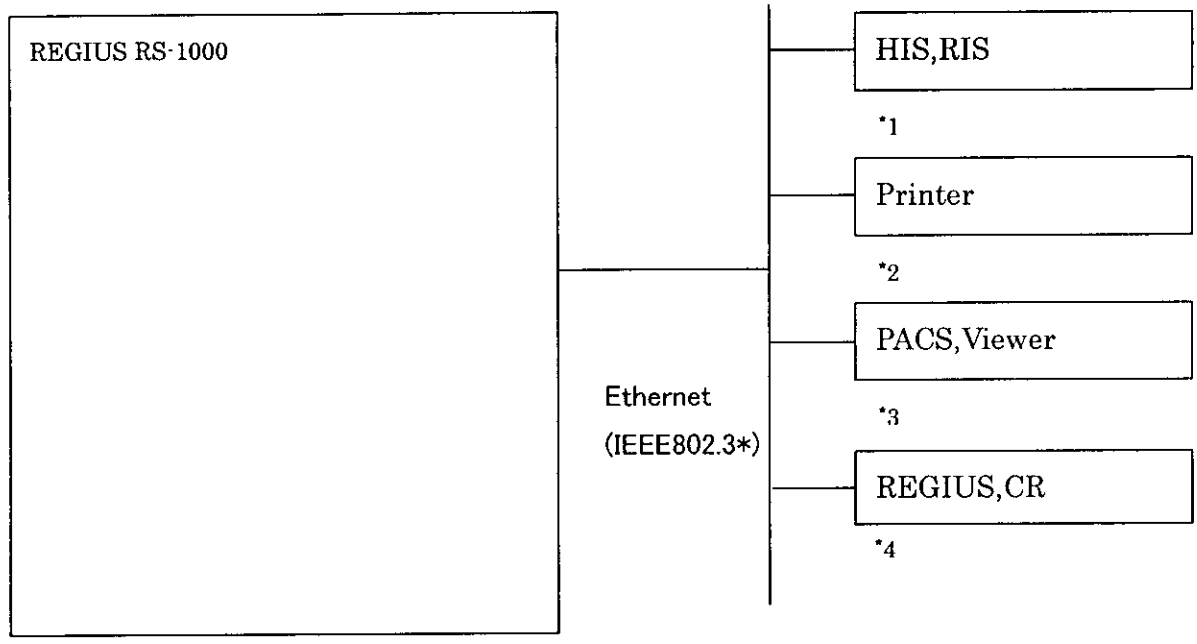
Note) This product is designed intended for exclusive use with a radiographer, and not for the purpose of doctor's diagnosis.

The REGIUS RS-1000 has the following feature.

1. The function to do an image processing to the image data received from the CR modalities.
   The kinds of the image processing are as follows:
   1) Adjusting the Contrast:
      Achieve a clearly depicted image (with clear minimum density).
   2) Re-sampling and Resizing
      The function that re-samples and resizes the image data according to need.
   3) F-processing:
      Improve dill or poorly modulated (lacking in contrast) images (to give definition to details). These process doses not affect density.
   4) E-processing:
      To improve the image that is not possible to be fully expressed by the film latitude due to the wide distribution of the subject.
   5) H-processing
      Hybrid processing is frequency enhancement processing and equalization processing based on multi-resolution analysis.
   6) Masking
      Fills in black the area on the frame where the X-ray is not irradiated.
   7) Stitching
      This function that manually or automatically recognizes the long body part and assists the user to stitch each body part to create a composite image. The user checks all alignments done automatically. The image can be divided into several small images before output to a storage device or film printer.
      Note) This feature requires cassette-type CR in addition connected.
2. The function that displays all information attached with the medical image, such as patient related information, study information, and so on. The ability to confirm, modify or update this information manfully or by connecting to RIS (Radiology Information System) or HIS (Hospital Information System) is also provided.
3. Images belong to the same study can be separated into different studies when necessary, and the different studies also be combined into a single study.
4. The function to add or modify digital marker, grid, scale, and so on.
5. The function that stores images data temporary before transferring them any further. Oldest images will be erased automatically to make sure of the hard-disk capacity for continuously operation.
6. The function that outputs the image data to a storage device, such as PACS (Picture Archiving and Communication System), and a film printer.
7. The function that retrieves past image data from a storage device. The retrieved image data may be re-processed then output to a film printer and so on.

9. Diagram of Layout and Interconnections

The figure of the layout and the mutual connection of the system



*1) DICOM Modality Worklist Information Model - FIND
DICOM Modality Performed Procedure Step SOP Class
*2) DICOM Basic Grayscale Print Management Meta SOP Class
*3) DICOM Computed Radiography Image Storage
*4) DICOM Computed Radiography Image Storage
Grayscale Softcopy Presentation State Storage SOP Class
DICOM Storage Commitment Push Model SOP Class

10. Safety Information

REGIUS RS-1000 introduces no new safety and efficacy issues other than those already identified with the predicate device. The results of a hazard analysis, combined with the appropriate preventive measure taken indicate that the device is of minor level of concern as per the "Guidance for the Content of Premark Submissions for Software Contained in Medical Devices".

11. Substantial Equivalence to Predicate Device

The REGIUS RS-1000 is substantially equivalent to Fuji CR Console Plus (Flash Plus IIP), 510(k) number: K041990.

Comparison of the principal characteristics of the two devices which are pertinent to specification performance is shown below.

1) Hardware

	Medical Device Applied for approval	Approved Medical Device Approval No. K041990
Feature	REGIUS RS-1000	Fuji Flash Plus IIP
Minimum Basic Computer Configuration	Computer "Off the Shelf" · Desktop or Tower · CPU: Pentium 4 · Bus: PCI · RAM: 1024MB · Hard Drive: 40GB · Floppy Drive: 3.5" · CD-ROM · Keyboard · Mouse	Computer "Off the Shelf" · Desktop or Tower · CPU: Pentium 4 · Bus: ISA/PCI · RAM: 512MB · Hard Drive: 40GB · Floppy Drive: 3.5" · CD-ROM · Keyboard · Mouse
Operating System Software	Microsoft Windows 2000 or Windows XP	Microsoft Windows 2000 or Windows XP
Ethernet Capability & Type	Yes:LAN	Yes:LAN
Image transfer	via DICOM 3.0 & Via proprietary protocol	via DICOM 3.0 & Via Fuji DMS Network
Image Display	16" color 1MP LCD	19" color 2MP LCD with Touch screen
Image processing functions	Yes, enhanced	Yes, enhanced
Image viewing & orientation functions	Yes, enhanced	Yes, enhanced
Connects to Image Recorders (Printers)	Yes	Yes

2) Software

Feature	REGIUS RS-1000	Fuji Flash Plus IIP	
Image processing	a. F-processing F-Processing is a form of image processing which modifies image spatial frequency characteristics, so that structures of body parts are displayed more sharply.	a. Gradation/Edge enhancement Along with gradation, edge enhancement as well as DRC Fuji image processing makes image quality consistently good, so the technologist spends less time manipulating the image.	Same as the approved device
	b. E-processing E-processing allows an image with a wide dynamic range to be converted to one with a smaller dynamic range which is easier to view.	b. DRC (Dynamic Range Control) DRC improves visualization of areas with different densities in the same image.	Same as the approved device
	c. H-processing H-Processing is the method of frequency Processing that uses the resolution of the image in multi resolution space. This adjusts the sharpness of the image and compress the dynamic range.	c. MFP (Multi-objective Frequency Processing) MFP enables enhancement of both small and large structures at the same time as well as better visualization of areas with different densities.	Same as the approved device
	d. Masking Masking blacks out areas outside the field of X-ray exposure on the image.		Additional feature
	e. Re-sampling and Resizing The functions change the resolution of the image, using digital image interpolation according to need.		Additional feature
	f. Stitching Stitching assembles the composite image from the images read out the photostimulated luminescence plates which had been positioned such that the two adjacent plates overlap each other at the exposure. This manually or automatically adjusts the image positions which are matched with each other.		Additional feature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2005

Konica Minolta Medical & Graphic, Inc.
% Mr. Shinichi Yamanaka
Safety Department
Cosmos Corporation
319 Akeno, Obata-cho, Watarai-gun
Mie-ken, 519-05
JAPAN

Re: K051521
Trade/Device Name: Medical Image Processing Workstation, REGIUS RS-1000
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 6, 2005
Received: June 14, 2005

Dear Mr. Yamanaka:

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) : K051521

Device Name : Medical Image Processing Workstation, REGIUS RS-1000

Indications For Use:

Receive and process electronic images of patients. The REGIUS RS-1000 is NOT intended for use with digital mammography system.

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 K051521