K051523

510(k) Summary

as required by 807.92

JUL 20 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 CONSOLE CS-2000 and REGIUS CONSOLE CS-3000, 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 CONSOLE CS-2000 and CS-3000 comply 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 CONSOLE CS-2000 and CS-3000 are KONICA MINOLTA CR CONSOLE.
REGIUS CONSOLE CS-2000 and CS-3000 control and manage the direct type CR such as REGIUS MODEL 370 that is directly connected to the Control Unit and the cassette type CR such as REGIUS MODEL 170 and 190 that is connected via the network.
REGIUS CONSOLE CS-2000 and CS-3000 have the hard disk for storing the digital images.
REGIUS CONSOLE CS-2000 and CS-3000 consist of a console with the touch panel function, a keyboard and a mouse for input, and a barcode scanner.
It can be connected to up multiple direct type CR and multiple cassette type CR, the image read by any reader in the system will be displayed on the REGIUS CONSOLE CS-2000 and

CS-3000 by which the objective cassette was registered. The image read by each reader will be displayed in real time in synchronization with the reader operation.

REGIUS CONSOLE CS-2000 and CS-3000 process the images received from the reader device with the auto gradation processing function, etc., and send them to the connected devices, such as the host computer or the CR printer.

In the case that patient registration is made at each X-ray room, the operator can search the patient information or examination information via "Examination Search Screen". On the other hand, when the facility has a separate reception, the operator can display and browse the registered Examination Information and Patient Information using "Examination List" screen. In this case, use of an ID Registration System will be necessary.

The console has the following feature.

1. The feature of subscribing patient information (the name, the age, the sexuality, the ID and so on) to display, to choose and to correct or, it is the feature to receive patient information and examination information (the body part, the exposures condition and so on) of the patient and to display, to choose from the hospital-information-system and to correct it.
2. The function to enter (the choice) examination information (the body part, the exposures condition and so on).
3. The function to specify the reading condition (the sampling pitch, the reading sensitivity of the sensor and so on) of the image information at the Reader section.
4. The function to require the reading of the image data of the Reader section.
5. The function to receive image data from the Reader section.
6. The function to display the image data which was received from the Reader section. Image data is culled to fixed size and is displayed.
7. It temporarily saves the image data which was received from the Reader section. The feature
8. The function to do an image processing to the image data which was received from the Reader section.

The kind of the image processing

1) Adjusting the Contrast:
Achieve a clearly depicted image (with clear minimum density).

2) F-processing:
Highlight fine detail in the image, or enhance detail that has been blurred. These process doses not affect density.

3) 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.

4) H-processing
Hybrid processing is frequency enhancement processing and equalization processing based on multi-resolution analysis.

5) Masking
Fills in black the area on the frame where the X-ray is not irradiated.

6) Rotating/Flipping
Rotate/Reverse the image.

7)Re-sampling and Resizing
The function that re-samples and resizes the image data according to need.

8) Stitching
The function that manually or automatically recognize the long body part and stitch each body part to create a composite image. 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.

9) Grid Suppression
The function suppresses the grid and moire patterns within the image exposed with the grid.

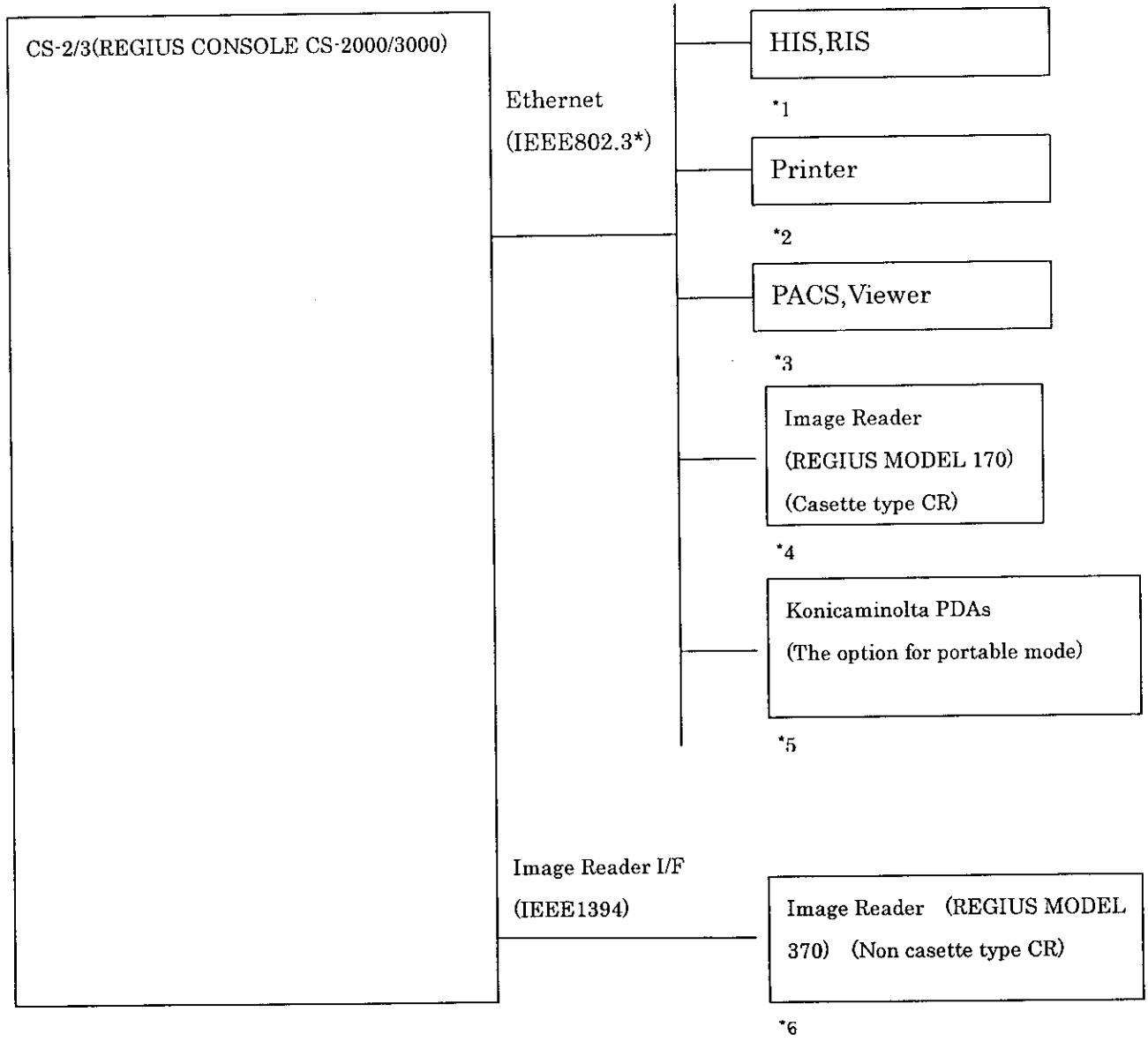
9. The function to add digital marker patient information and so on to the image data which was received from the Reader section.
10. The function that the printer outputs the image data which was received from the Reader section in the host computer and so on
    The REGIUS CONSOLE CS-2000 utilizes Discrete Cosine Transform (DCT) as of standard irreversible compression techniques to output the image data to Floppy Disk.
    The REGIUS CONSOLE CS-3000 is not utilized Discrete Cosine Transform (DCT)

    Note) Console is designed in the purpose that the radiographer uses and is never used for a diagnosis purpose.

11. Portable mode
    The optional the portable mode is the practical use form which PDA(Personal Digital Assistance) done so that it could carry a bar cord leader department and photography (condition) information from REGIUS CONSOLE CS-2000 and CS-3000 so that a bar cord can register cassette in that place in case of portable photography in the hospitalization ward and so on was used for.

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
*2 DICOM Basic Grayscale Print Management Meta SOP Class
*3 DICOM Computed Radiography Image Storage
DICOM Storage Commitment Push Model SOP Class
*4 Konicaminolta original protocol
*5 Konicaminolta original protocol
*6 Konicaminolta original protocol

10. Safety Information

REGIUS CONSOLE CS-2000 and CS-3000 introduce 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 May 29, 1998 issue of the "Guidance for the Content of Premark Submissions for Software Contained in Medical Devices".

11. Substantial Equivalence to Predicate Device

The REGIUS CONSOLE CS-2000 and CS-3000 are 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

Feature	REGIUS CONSOLE CS-3000	REGIUS CONSOLE CS-2000	Fuji Flash Plus IIP
Minimum Basic Computer Configuration	Computer "Off the Shelf" • Desktop or Tower • CPU: Pentium 4 • Bus: PCI • RAM: 1GB • Hard Drive: 80GB • Floppy Drive: 3.5" • CD-ROM • Keyboard • Mouse • Barcode scanner	Computer "Off the Shelf" • Desktop or Tower • CPU: Pentium 4 • Bus: PCI • RAM: 512MB • Hard Drive: 80GB • Floppy Drive: 3.5" • CD-ROM • Keyboard • Mouse • Barcode scanner	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 • Barcode scanner
Operating System Software	Microsoft Windows XP	Microsoft Windows XP	Microsoft Windows 2000 or Windows XP
Ethernet Capability & Type	Yes:LAN	Yes:LAN	Yes:LAN
Image transfer	via DICOM 3.0 & Via proprietary protocol	via DICOM 3.0 & Via proprietary protocol	via DICOM 3.0 & Via Fuji DMS Network
Image Display	15" color 1MP LCD with Touch screen	15" color 1MP LCD with Touch screen	19" color 2MP LCD with Touch screen
Image processing functions	Yes, enhanced	Yes, enhanced	Yes, enhanced
Image viewing & orientation functions	Yes, enhanced	Yes, enhanced	Yes, enhanced
Connects to Konicaminolta Image Readers	Yes	Yes	No
Connects to Konicaminolta Image Recorders(Printers)	Yes	Yes	Yes
Connects to Konicaminolta PDAs(The option for portable mode)	Yes	No	–

2) Software

Feature	REGIUS CONSOLE CS-3000	REGIUS CONSOLE CS-2000	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. Grid Suppression The function suppresses the grid and moire patterns within the image exposed with the grid, processing by filtering.		d. GPR (Grid Pattern Removal) GPR removes stationary grid pattern to suppress moire patterns within an image.	Same as the approved device
	e. Masking Masking blacks out areas outside the field of X-ray exposure on the image.			Additional feature
	f. Re-sampling and Resizing The functions change the resolution of the image, using digital image interpolation according to need.			Additional feature
	g. 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
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JUL 20 2005

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

Re: K051523
Trade/Device Name: Medical Image Processing Workstation, REGIUS CS-2000/CS-3000
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) : K051523

Device Name : Medical Image Processing Workstation, REGIUS CS-2000/ CS-3000

Indications For Use:

Receive and process electronic images of patients. The REGIUS CS-2000/CS-3000 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 K051523