K071436

510(k) Summary

JUN 27 2007

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
2970 Ishikawa-machi, Hachioji-shi, Tokyo 192-8505, Japan
Phone: 81-42-660-9607
Fax: 81-42-660-9588

2. Official Correspondent

Koji Matsushima (Mr.)
Manager
Standards & Regulations Department
Quality Assurance Center

3. Date of Submission

May 21, 2007

4. Establishment Registration No.

3003769120

5. Device Trade Name

REGIUS Unitea

6. Common Name

Medical Image Processing Work Station

7. Classification

Class II, 90 LLZ, 21 CFR 892. 2050, Picture archiving and communications system

8. Predicate Device

REGIUS CS-2000 and CS-3000, 510(k) number: K051523 cleared on Jul.20,2005

9. Description of Device

REGIUS Unitea is a software which is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. REGIUS unitea software controls and manages the cassette type CR (Computed Radiography) such as REGIUS MODEL 170,190 and 110 that is connected via the network. REGIUS Unitea receives and displays images from other DICOM compliant modalities connected via the network and whole use digital media such as DVD/CD-R, DSC and USB memory cards connected as disk drives

REGIUS Unitea software has the following set of features.

1. Feature to automatically obtain patient demographic information (Name, Age, Sex, Date of Birth, etc) from Hospital Information Systems.
2. Feature to specify the reading condition (Sampling pitch, Reading Sensitivity of the sensor and so on) of the connected CR device.
3. Receive and store image data from REGIUS MODEL 170, 190 and 100 CR, other DICOM compliant modalities and digital media (such as DVD/CD-R, DSC and USB memory cards).
4. Display image data received from the REGIUS MODEL 170, 190 and 100 CR, other DICOM compliant modalities and digital media (such as DVD/CD-R, DSC and USB memory cards).
5. Feature to apply image processing to images received from REGIUS MODEL 170, 190 and 100 CR.

Image processing applied includes:

1) Contrast and Density Adjustments.
2) F-processing: Frequency processing that highlights fine details in the image, or enhances detail that has been blurred, without affecting density.
3) E-processing: Equalization processing that improves the image quality that cannot be fully expressed by the film latitude due to wide distribution of the subject.
4) H-processing: Hybrid processing which combines frequency enhancement processing and equalization processing based on multi-resolution analysis.
5) I- processing: Integral processing that automatically adjusts luminance (film density) and contrast of an image.
6) Masking: Fills black on the area of the frame where X-ray is not irradiated.
7) Rotating/Flipping: Rotate/Reverse an image.
8) Re-sampling and Resizing: Function that re-samples and resizes the image data.
9) Stitching: Function that manually or automatically recognizes long body part and stitch multiple images to create a composite image. The stitched image can be divided into several small images before outputting to a storage device or film printer.
10) Grid Suppression Function to suppress the grid and moire patterns within the image exposed with the grid
11) Function to add digital marker for patient information and to add annotations to the image data
12) Function that outputs image data to a printer, other DICOM devices and digital media.

10. Intended Use

The REGIUS Unitea software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The REGIUS Unitea software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The REGIUS Unitea

software can process and display images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The REGIUS Unitea must not be used for primary image diagnosis in mammography.

11. Substantial Equivalence to Predicate Device

REGIUS Unitea is substantially equivalent to our REGIUS CS-2000 and CS-3000, 510(k) number: K051523. Comparison of the principal characteristics of these devices is shown in the Section 3.

12. Safety Information

REGIUS Unitea 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 May 11, 2005 issue of the "Guidance for the Content of Premark Submissions for Software Contained in Medical Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 27 2007

Konica Minolta Medical & Graphic, Inc.
% Mr. Russell Munves
US Agent and Attorney
Storch, Amini, & Munves, P.C.
140 East 45th St., 25th Floor Two Grand Central Tower
NEW YORK NY 10017

Re: K071436
Trade/Device Name: REGIUS Unitea
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 21, 2007
Received: May 23, 2007

Dear Mr. Munves:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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) :

Device Name : REGIUS Unitea

Indications for Use:

The REGIUS Unitea software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The REGIUS Unitea software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The REGIUS Unitea software can process and display medical images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The REGIUS Unitea must not be used for primary image diagnosis in mammography.

Prescription Use__X____ 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071436