K051998

510(k) Summary : Device Modification

as required by 807.92

1. Company Identification

NOV - 3 2005

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2. Official Correspondent

Masafumi Saito(Mr.)
Department TS
Advanced Technology Division
R & D Center

3. Date of Submission

July 11th, 2005

4. Device Trade Name

Direct Digitizer REGIUS MODEL 170

5. Common Name

Direct Digitizer

6. Classification

Medical image digitizers were reviewed by the Radiology Panel and are classified in Class Ⅱ per 21 CFR 892. 1650.

7. Predicate Device

Modified Direct Digitizer REGIUS MODEL 170 is substantially equivalent to our current Direct Digitizer, MODEL 170, 510(k) number: K023061.

8. Description of Device

The Direct Digitizer, REGIUS MODEL 170 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette, and reads the image recorded on the Plate by inserting a cassette in the entrance slot of the REGIUS MODEL 170. By means of laser scan and photoelectric method, the device reads the X-ray image data created in form of a latent image on the Plate exposed by an external X-ray generating device, and converts the read data into digital. The signal processing is made to the digital image data such as the digital filtering, the gain-offset correction and the shading collection. Then the REGIUS MODEL 170 is capable of transferring the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices.

The modifications are 1) Applicable cassette size is increased. 2) Read-Only cassettes are added, 3) Exposure-Only cassettes are added, and 4) Function of a reader console is upgraded.

The purpose of modification is to enable to use of multiple cassettes to obtain images of long areas of anatomy and then to present the images as a single composite image (Long Length Imaging feature), and to obtain images to verify the position for a radiotherapy location.

・Long Length Imaging feature

This is suitable for ordinary exposure of the skeletal system such as the whole spine or the whole lower leg, and is used for measurement purposes, such as measurement of skeletal deformation. 14x42in, 14x51in, 11x28in, 10x36in sizes are required for the exposure size, and the exposure is made onto a photostimulable phosphor plate formed by joining a number of photostimulable phosphor plates (Plate) of regular size.

- Read-Only Cassettes and Exposure-Only Cassettes used for Long Length Imaging feature.

Exposure-Only Cassette can not be set to REGIUS MODEL 170, because size does not match.

Read-Only Cassette can be set to REGIUS MODEL 170.

In order to set to REGIUS MODEL 170, the plates are removed from the Exposure-Only Cassette and loaded to Read-Only Cassettes.

When the image is read onto REGIUS MODEL 170, the cassette is fed into the device, the photostimulable phosphor plate contained in the cassette uncovered and the image information recorded on the plate scanned and read out.

REGIUS MODEL 170, using Exposure-Only cassettes that incorporate multiple

plates (joined) for exposure and Read-Only cassettes that incorporate a single plate so that the cassette size is small enough to be accepted by the device, enable image reading similar to ordinary X-ray exposure by replacement of the photostimulable phosphor plates.

- Radiotherapy localization for Linac Graphy

Linac Graphy is used as part of linac (Linear Accelerator) treatment, a kind of radiotherapy (in cases of external radiation radiotherapy).
First of all, design a treatment plan including the irradiation field size and irradiation amount so that the dose to which the patient is exposed during radiotherapy is minimized.
To make a test exposure in order to design the treatment plan, expose the body part positioned as it would be during actual treatment using a CT, etc., and develop the treatment plan based on the information thus obtained.
Then, mark the treatment-target area of the body part that is actually positioned on the treatment table for linac, and, after checking the treatment position using the photo for position verification by linac graphy technology, initiate the treatment.
One method of photographic procedure to produce images used to verify the position is the method using REGIUS MODEL 170, Photostimulable Phosphor Plate and exposure cassette containing metal plate to prevent over exposure problem where all of the exposed images are recorded on the photostimulable phosphor plate exactly as for general X-ray exposures.

- Read-Only Cassettes and Exposure-Only Cassettes used for Radiotherapy localization

When the image is read on REGIUS MODEL 170, the cassette is fed into the device, the photostimulable phosphor plate contained in the cassette uncovered and the image information recorded on the plate scanned and read out.
Because the above mentioned cassette for linac graphy contains a metal plate, it is difficult to feed such a cassette into the device due to its weight that is relatively greater than that of a normal X-ray cassette. Therefore, REGIUS MODEL 170, using Exposure-Only cassettes incorporating a metal plate and Read-Only cassettes with photostimulable phosphor plates processed in the device after exposure, enable image reading identical to ordinary X-ray exposure by replacement of the photostimulable phosphor plate after exposure.

Risk analysis is the same as our current REGIUS MODEL 170, K023061.
(We consider no new risk will arise and therefore we did not conduct a new risk analysis.)

Software information is also the same as current REGIUS MODEL 170, K023061.

Labeling (User operation manual) is added to current REGIUS MODEL 170.
Additional part of Labeling from the current REGIUS MODEL 170 is attached.
For more information, please refer to the attachments.

9. Intended Use

The Direct Digitizer, REGIUS MODEL 170 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices.
REGIUS MODEL 170 is used to obtain image data of long areas of anatomy such as the whole spine or the whole lower leg.
REGIUS MODEL 170 is also used to obtain image data to verify the position for a radiotherapy location.
It is designed intended to use in a clinic, a radiology department in a hospital and in other medical facilities.
It is not intended for use with digital mammography system.

10. Substantial Equivalence to Predicate Device

The Direct Digitizer, REGIUS MODEL 170 is substantially equivalent to our current Direct Digitizer REGIUS MODEL170, 510(k) number: K023061. Comparison of the principal characteristics of the two devices is shown in the attachments.

11. Compliance standards

The Direct Digitizer, REGIUS MODEL 170 complies with the following standards:

Safety standard	:UL60601-1, IEC60601-1
Electromagnetic Compatibility	: FCC, IEC60601-1-2
Radiation safety	: 21 CFR 1040.10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
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AUG 23 2013

Re: K051998
Trade/Device Name: Direct Digitizer REGIUS Model 170
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 20, 2005
Received: September 30, 2005

Dear Mr. Saito:

This letter corrects our substantially equivalent letter of November 3, 2005.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) : K051998

Device Name : Direct Digitizer, REGIUS Model 170

Indications For Use:

The Direct Digitizer, REGIUS MODEL 170 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices.
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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 K051998