K110033

SEP 15 2011

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

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Date Summary Prepared: **May 17, 2011**

Device Name:

Trade Name(s) :	feel-DRCS
Classification Name :	Picture archiving and communications system.
Common Product Name :	Radiological Image Processing System.
Panel :	Radiology
Product Code:	LLZ

Predicate Device Information:
K091364 / dicomPACS DX-R 1.6

Device Description:

This medical imaging device software is composed of a combination of many functions. The functions include interfacing X-ray detector, integration X-ray generator, networking PACS, image enhancement processing and editing image/information. The name of this software is called DROC(Digital Radiography Operation Console)

The operational process of feel-DRCS is described below:

① Input or select study information
patient ID/Name, body part and projection, if you can use DICOM Modality Worklist Management SCP, you select in worklist.

② Setup exposure parameter of X-ray generator

③ After exposure, this software acquires raw images from X-ray Detector.

④ After acquisition of raw image, this software corrects raw image.

⑤ After correction of raw image, this software processes with noise reduction, enhancement, auto windowing etc.

⑥ After processing of corrected image, this software displays an image on the monitor.

⑦ If this software is connected with PACS network, it transfers images to PACS Server or DICOM film printer.

Intended Use:

feel-DRCS software using a digital X-ray detector is the digital X-ray image processing system designed to acquire images and process acquired images efficiently.

The main features of this software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, optimizing window level and width of acquired images, rotating images, zooming images, measuring images and so on.

feel-DRCS is compatible with DICOM 3.0 standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.0 by using DICOM and network systems.

feel-DRCS is not approved for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data.

feel-DRCS is not approved for the acquisition of mammographic image data.

Comparison to Predicate Device(s):

This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Product name	Predicate device (K091364) dicomPACS DX-R 1.6	New device feel-DRCS
Intended use	Acquiring, viewing, editing and storing radiographs and related patients images	same
Intended user	Radiologist	Radiologist
Operating system	Microsoft Windows XP/Vista/7	Microsoft Windows XP/7
Network	10/100/1000 Ethernet	10/100/1000 Ethernet
Monitor	19 inch Monitor(1280 X 1024, etc)	Above 19inch Monitor(Above 1280 X 900)
User interaction / input	Mouse, Keyboard, Touch Monitor,	Mouse, Keyboard, Touch Monitor,
Multi-user	Available But at a time, only one user can use it.	Available But at a time, only one user can use it.
Import / export images	Yes	Yes
Acquisition devices	Computed Radiography Digital X-ray Detector	Computed Radiography Digital X-ray Detector

Product name	Predicate device (K091364) dicomPACS DX-R 1.6	New device feel-DRCS
Imaging interfaces	Detector dependent	Detector dependent
Image organization	Yes Patient ID/Name/Study instance UID	Yes Patient ID/Name/Study instance UID
Image search available	Yes	Yes
Image storage	Yes	Yes
Database storage	Yes	Yes
Database software	MS-SQL	MS-Access
Image viewing	Yes	Yes
Image measurement	Yes	Yes
Image annotation	Yes	Yes
Image operations	Yes	Yes
security	Yes(Priority by User)	Yes(Priority by User)
DICOM 3.0 Compatibility	Yes	Yes
Generator Control	OK	OK
Generator Control protocol	Generator dependent	Generator dependent
Raw image data processing	OK	OK
Post image data processing	OK	OK
RIS Code manager	OK	OK

Summary of non-clinical testing:
This section is not applicable.

Conclusion
Based on the information provided in this summary we conclude that this device is substantially equivalent to the predicate device K091364.

003 (3)

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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REPUBLIC OF KOREA

Re: K110033
Trade/Device Name: Radiological Image Processing System/feel-DRCS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 8, 2011
Received: August 12, 2011

Dear Mr. Ho Dong Yang:

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,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

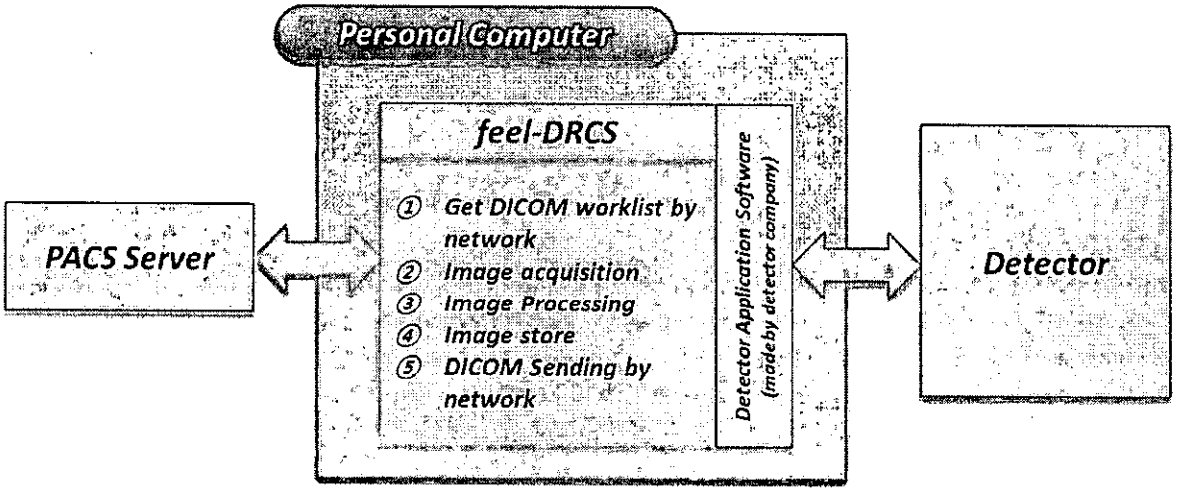
- 510(k) Number (if known): **110033**

- Device Name: Radiological Image Processing System / **feel-DRCS**

- Indications for Use:

feel-DRCS software, used together with digital X-ray detector is the digital X-ray image processing system designed for acquiring images and processing acquired images efficiently. The main features of this software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, optimizing window level and width of acquired images, rotating images, zooming images, measuring images and other features used for imaging processing.
feel-DRCS is compatible with DICOM 3.0 standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.0 by using DICOM and network systems.
feel-DRCS is not approved for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data.

Following is the diagram of feel-DRCS software system.



The main functions of feel-DRCS as follows:

A. Acquisition and storage of digital X-ray images from a digital X-ray Detector.
B. Input Study information (patient information, exam information).
C. Management of DataBase of stored (archived) images.

D. Image processing for enhancement of archived images.
E. Review of stored images.
F. Edit of image(Shutter or crop, insert Marker("L", "R"), Window width/level etc)
G. DICOM Functions(DICOM Storage, DICOM Worklist, DICOM Print, etc)
H. In case of DR full system(X-ray machine and generator and Digital X-ray detector and etc) or need a interface with installed X-ray System in the feel-DRCS.
   ① Ability to configure X-ray exposure condition (kVp, mA, Sec etc) for various body parts and positions.
   ② Communication between Generator Console and feel-DRCS.

** This X-ray generator control function depends on the X-ray Generator company. Because feel-DRCS can only interface and control by the algorithm provided by the X-ray Company. And feel-DRCS can only select or change values of X-ray exposure parameters(kVp, mA, Second or kVp, mAs) according to defined value of each X-ray company. The feel-DRCS doesn't control exposure and electrical change and calibration X-ray. So, before exposure of X-ray, radiological technician should check the X-ray exposure conditions in the console of X-ray Generator.*

** If the X-ray generator doesn't allow interface with external software(ex. Feel-DRCS), the software cannot interface with X-ray Generator.*

Users
A. For acquisition of Digital X-ray image by Digital X-ray Detector.
B. For development or Production of Digital Radiography Retrofit system on the conventional X-ray system.

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 In Vitro Diagnostic Devices (OIVD)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K110033