JUL 0 3 2014

K140869/
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## 510(k) Summary

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

Date: Mar. 15, 2014

1. Company and Correspondent making the submission:

Name – GP&P Co., Ltd.
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Contact – Mr. SungChul Ahn / RA Manager

2. Device :

Trade/proprietary name : DCAS i
Common Name : Picture archiving and communications system
Classification Name : System, image processing, radiological

3. Predicate Devices :

Manufacturer: : GE Medical Systems In formation Technologies
Device: : Centricity Cardiology CA1000
510(k) Number: : K042525 (Decision Date – 10/01/2004)

4. Classifications Names & Citations :

21CFR 892.2050, LLZ, Picture archiving and communications system, Class2

5. Description :

1) General Description

The DCAS i is an equipment for providing medical treatment services of a good quality in cardiology and developing into an advanced medical institution through innovative work improvement, in order to keep up with the rapidly changing era of medical information. The DCAS i, which has an improved high-speed image processing engine,

processes in the method of multi-threading to display multiple DICOM Cine images in a simultaneous way. It allows the user to look up, keep, and manage all the medical images used in cardiology with XA, ECHO, and IVUS images as the basic ones. The DCAS i sends even high-capacity images within only a few seconds and expresses them on the basis of the GIGABIT network environment of its own. The enhanced convenience of its user interface allows the user to view, arrange, and manage the needed image by only controlling it in a simple way. Also, as the user can arrange images as he or she wants regardless of the sort of the images, the user can compare and analyze the images of all the equipments of cardiology on this system. The user can record the images of the patient wanted on a CD or DVD by only controlling a few times. Here, the exclusive viewer allows the user to check the recorded images of the patient in all sorts of environment. In addition, the user can edit and convert the DICOM Cine images into AVI and static images, and this makes it easier to edit various images and frame a report. Only the user authorized by using the Internet can use this system based on the Web as needed, and in an environment with a wireless network built, the user can look up data through a mobile device.

**2) Main Function**

(1) Server

The Server controls each module and communication and saves the data files and the database.

Before linking each module to the Server, the communication test gets done if each module can be connected to the Server; and when the connection is available, the user gets checked if he or she has the authority to access the Server. When a user with no authority to access the Server tries to access or a user tries to access on another system with an ID which is already accessed to the Server, the user gets forced to log out.

The Server saves the files sent from the DICOM Acquisition and also

saves the data information and patient information in the SQL.
Also, when the device for lookup requests for data files and data information, the Server provides the pertinent files and information to the device for lookup that has requested for them.

(2) Acquisition

The DICOM files get sent from the DICOM output device (Angio, ECHO, IVUS) to the DICOM Acquisition by using the DICOM network based on the DICOM 3.0 standard. The DICOM files get sent from the DICOM Acquisition to the DATA Server. When the DICOM files get sent, the patient information from among the DICOM header information gets saved in the SQL DB, and the image files get saved in the FTP of the DATA Server. When image files get saved, they get converted into JPG files to be outputted on the Web and the Mobile; also, the Thumbnails to be shown on the list get saved together.

(3) CS View

Dental Reformat makes it possible to reconstruct Panoramic and Cross sectional images. Conventional imaging solutions are supported, and also new imaging solutions such as Volume Rendering, 3D Scout are supported. The layout and images are optimized for Reporting

The CS View is a special viewer that perfectly materializes DICOM, which is an international standard of medical images. It allows the user to rapidly and accurately look up and compare images of a variety of format of various medical devices in high definition. It rapidly provides images to the user with the Device Independent Bitmap (DIB) engine, and also allows the user to compare several DICOM images at the same time by employing the 'multi-threading' system.
The user can look up and search the patients registered on the server and the data saved. The CS View provides simple measuring functions for the images looked up.
The CS View supports CD Recording function and the Export function of a variety of format. It also supports a codec to allow the user to

convert images into high-quality image files.

(4) WEB View

The Web View uses a UI which is consistent with those of the DCAS i cs and the DCAS i mobile for the user to easily adapt to. It allows the user to search and look up images not only within the hospital but anywhere with a PC connected to the Internet. If you have a PC with the Internet and Web surfing available, you can look up and check patients' images on the Web wherever in the same way you use the DCAS i cs. As the user accesses through a Web browser, there is no issue of hardwares or softwares occurring unexpectedly while the user is installing the software.

(5) Mobile View

The Mobile View is made of the most frequently used functions in the DCAS i cs. As it is optimized for latest mobile devices, you can actively utilize it while you are having a conversation with a patient in the environment with a wireless network built. Also, the doctors can search items on behalf of the patient who is not able to move freely to explain to the patient..

In addition, the user can check and comment on the images whenever wherever, even overseas or out of the hospital, if only communication is available to convey accurate information and give instructions to the doctor in charge in the field.

**3) Information of the image format**

DCAS i can load only DCM files and save results as DCM, BMP and JPG files.

- DCM : DICOM (Digital Image Communication in Medicine) is a Standard Protocol to exchange and transfer the data acquired by Medical Image devices such as a CT, MR, 3D US, etc. It is designated as a Standard Protocol by ACR-NEMA (American College of Radiology-National Electrical Manufacturers Association) and now adopted by most Medical Imaging Devices. DCAS i 2.0 is adaptable technically for all data of DICOM 3.0.

Reference : Digital Imaging and Communications in Medicine (DICOM) ACR-NEMA Standards Publication PS 3.1~PS 3.16 2003.

- BMP : The standard bit-mapped graphics format used in the Windows environment. By convention, graphics files in the BMP format end with a BMP extension. BMP files store graphics in a format called device-independent bitmap (DIB).
- JPG/JPEG : Short for "Joint Photographic Experts Group", the original name of the committee that wrote the standard. JPG is one of the image file formats supported on the Web. JPG images support 16 million colors and are best suited for photographs and complex graphics.

**4) Compression**

- Compression Method : Lossless Compression

6. Indication for use :

The DCAS i allows the user to look up, keep, and manage all the medical images used in cardiology with Angio, ECHO, and IVUS images as the basic ones. It allows the user to view, arrange, and manage the needed image by only controlling it in a simple way. Also, as the user can arrange images as he or she wants regardless of the sort of the images, the user can compare and analyze the images of all the equipments of cardiology on this system. The user can record the images of the patient wanted on a CD or DVD. Here, the exclusive viewer allows the user to check the recorded images of the patient in all sorts of environment. In addition, the user can edit and convert the DICOM Cine images into AVI and static images to use them for editing various images and framing a report. Only the user authorized by using the Internet can use this system based on the Web, and in an environment with a wireless network built, the user can look up data through a mobile device.

DCAS i images can be used for reference purposes only and cannot be used for precise readings.

7. Comparison with predicate device :

GP&P Co., Ltd., ensures that the DCAS i, Picture archiving and communications

system is substantially equivalent to Centricity Cardiology CA1000 of GE Medical Systems In formation Technologies.

The DCAS i described in this 510(k) has the same intended use and similar t echnical characteristics as the Centricity Cardiology CA1000 of GE Medical Sys tems *In formation Technologies*. The similarities and differences between these systems are described in the table shown above.

The similarities are as follows.

1. *Similarity of DICOM-Compliant, Architecture, Server, Security, Storage.*
2. *Similarity of System failure alert, Database Management.*
3. *Similarity of Web-Based Access, Thumbnail, Image Compression, Multi-frame support, Image Control, Play Control, Zoom*
4. *Similarity of Search Patient, Search Case Date, Search Modality, Sort.*
5. *Similarity of Common Measurement XA Analysis, Us Analysis.*

The difference is as follows.

*DCAS i provides mobile applications for iPads and Android Tablets, named "mobile View".*

In summary, The DCAS i does not introduce any new potential safety risks an d is substantially equivalent to and performs as well as the predicate device.

In conclusion, the DCAS i is substantially equivalent to Centricity Cardiology CA1000 of GE Medical Systems In formation Technologies.

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification GP&P Co., Ltd. concludes that DCAS i is safe and effective and substantially equivalent to predicate devices as described herein.

9. GP&P Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GP&P Co., Ltd.
% Mr. Charlie Mack, Principal Engineer
International Regulatory Consultants
12226 Washington Lane
PARKER AZ 85344

July 3, 2014

Re: K140869
Trade/Device Name: DCAS i
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 16, 2014
Received: June 24, 2014

Dear Mr. Mack:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number(if known): K140869

Device Name: Picture Archiving Communications System / DCAS i

Indications for Use:

The DCAS i allows the user to look up, keep, and manage all the medical images used in cardiology with Angio, ECHO, and IVUS images as the basic ones. It allows the user to view, arrange, and manage the needed image by only controlling it in a simple way. Also, as the user can arrange images as he or she wants regardless of the sort of the images, the user can compare and analyze the images of all the equipments of cardiology on this system. The user can record the images of the patient wanted on a CD or DVD. Here, the exclusive viewer allows the user to check the recorded images of the patient in all sorts of environment. In addition, the user can edit and convert the DICOM Cine images into AVI and static images to use them for editing various images and framing a report. Only the user authorized by using the Internet can use this system based on the Web, and in an environment with a wireless network built, the user can look up data through a mobile device.

DCAS i images can be used for reference purposes only and cannot be used for precise readings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Michael D. O'Hara