



Food and Drug Administration
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COMPAÑÍA MEXICANA DE RADIOLOGÍA CGR, S.A. de C.V.
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

August 17, 2016

Re: K161518
Trade/Device Name: PACS CORE/ENCORE™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 18, 2016
Received: June 21, 2016

Dear Mr. Alletto:

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,



For

Robert Ochs, Ph.D.
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)

K161518

Device Name

PACS CORE/ENCORE™

Indications for Use (Describe)

PACS CORE/ENCORE™ is a software device that receives digital images and data from various sources (such as, CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA. Typical users of this system are trained professionals, physicians, nurses, and technicians.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

May 23, 2016

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Carl Alletto
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McKinney TX, 75071 USA
Email: carl@otechimg.com
Phone: +1 469.684.1980

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: PACS CORE/ENCORE™
Common Name: Picture Archiving Communications System
Device Classification: 892.2050 System, Image Processing
Product Code: LLZ

Predicate Device: 21 CFR 807.92(a)(3)

Device Classification Name	system, image processing, radiological
510(k) Number	K092949
Device Name	IMAGEGRID RADIOLOGY VIEWER SYSTEM
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	09/24/2009
Decision Date	10/08/2009
Decision	substantially equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
summary	summary
Type	Traditional
Combination Product	No

Device Description: 21 CFR 807.92(a)(4)

The PACS CORE/ENCORE™ system is a PACS workstation capable of receiving DICOM 3.1 medical images. The System allows displaying studies that are not in the same place where the system is placed. With its Web features, it is possible to review, modify, and approve studies located in a server. General features are as follows:

- Integration to PACS systems and inter-connectivity with DICOM stations.
- Performing queries to storage systems in other workstations and/or servers to retrieve DICOM studies or images.

510(k) Summary of Safety and Effectiveness

- Image printing in Windows and DICOM printers.
- Selecting and ordering patient lists by date, study, name, gender or ID number.
- Importing and exporting images to DVD or CDROM in the following modes: DICOM DIR, DICOM files, JPEG or BMP.
- Importing NON-DICOM images to DICOM 3.0 format.
- Transfer of studies, images and reports via e-mail.
- Study Visualization by series.
- Cine feature.
- 3D reconstruction allowing: MPR (Multiplane Reconstruction)
- Integrated report feature with transcription through pre-set templates, digital dictation, and voice recognition.
- Possibility to integrate with a Radiology Information System (RIS).
- Work list follow-up; dictated study, transcribed study, and authorized study.
- Due to its Web features, it is possible to review, change and approve studies remotely.
- Complete Web Windows Presentation Foundation (XBAP) technology application.
- Windows Presentation Foundation desk application.

Indications for Use: 21 CFR 807 92(a)(5)

PACS CORE/ENCORE™ is a software device that receives digital images and data from various sources (such as, CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA. Typical users of this system are trained professionals, physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

PACS CORE/ENCORE™ device is a software product that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Testing

510(k) Summary of Safety and Effectiveness

The complete system configuration has been tested at the factory and the device has passed all in-house pre-determined testing criteria without significant failures. The data presented in the submission demonstrates that PACS CORE/ENCORE™ performs all required actions according to the functional requirements specified in the SRS and the User Manual with no errors that had an impact on safety or efficacy.

Conclusion: 21 CFR 807 92(b)(1)

The 510 (k) Pre-Market Notification PACS CORE/ENCORE™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. PACS CORE/ENCORE™ has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the “Level of Concern for potential hazards has been classified as “Moderate”.