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

July 18, 2017

Examion GmbH
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

Re: K170729
Trade/Device Name: Examion X-AQS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 5, 2017
Received: June 9, 2017

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170729

Device Name
Examion X-AQS™

Indications for Use *(Describe)*
The Examion X-AQS™ software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the 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. The Examion X-AQS™ system is compatible with the DICOM 3.x communications standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.x by using DICOM and network systems. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians. Contraindications: Examion X-AQS™ is not intended for creation of fluoroscopic/ radioscopic, or angiographic images. The main functions of the Examion X-AQS™ system are:
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 stored (archived) images, d) Image processing for enhancement of archived images, e) Review of stored images, f) Editing of images, g) DICOM conformance (e.g. DICOM Storage, DICOM Work list, DICOM Print, etc.), h) For a DR system (X-ray machine and generator and Digital X-ray detector, etc.) or a need to interface with installed X-ray system, the: • Ability to configure X-ray exposure condition (kVp, mA, Sec etc.) for various body parts and positions. • Communication between Generator Console and Examion X-AQS™.
The X-ray generator control function depends on the X-ray Generator company. The X-ray generator is not part of the Examion X-AQS™ system since the Examion X-AQS™ system can only interface and control the Generator by the algorithm provided by the X-ray Company. The Examion X-AQS™ system can only select or change values of X-ray exposure parameters (kVp, mA second or kVp, mAs) according to the defined value determined by each X-ray company. The Examion X-AQS™ system does not control exposure and electrical charge and calibration X-ray. If the X-ray generator does not allow interfacing with external software the Examion X-AQS™ software cannot be interfaced with X-ray Generator.

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.

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:

June 5, 2017

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

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

Trade Name:	EXAMION X-AQS™
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	K123650
Device Name	ARIX RAD ACQUISITION CONSOLE
Applicant	COMPANIA MEXICANA DE RADIOLOGIA CGR, S.A. DE C.V.
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	11/27/2012
Decision Date	02/20/2013
Decision	substantially equivalent (SE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
summary	summary
Type	Traditional

Device Description: 21 CFR 807 92(a)(4)

The EXAMION X-AQS system is an enterprise Picture Archiving and Communications System (PACS) used to handle DICOM digital medical images and other associated data.

The system enables the receipt of DICOM images from various imaging devices (modalities) like CT, MRT, US DICOM and enables their storage, retrieval, distribution,

image manipulation and examination for diagnostic purposes, annotation and report generation The EXAMION X-AQS software system is customizable and scalable to meet various enterprise functional and size requirements. It is a standard based system Integrating the Health Enterprise (IHE) profiles, Digital Imaging and Communications in Medicine (DICOM), Joint Photographic Expert Group (JPEG) and Health Level Seven (HL-7) protocol standards for managing digital medical images as well as patient data. The EXAMION X-AQS supports all types of diagnostic radiographic images, mammography, endoscopy and multi-frame studies. The EXAMION X-AQS console comprise of two major components:

- EXAMION X-AQS PACS Server: A server receives image data in DICOM format from archives, modalities and workstations via universal connections via the hospital network. EXAMION X-AQS PACS Server provides archiving for short term and long term archive. The system provider has to take own appropriate means like redundancy for safety against data loss.
- EXAMION X-AQS PACS Viewer: Client server system that is used to view, edit, manipulate, annotate, and analyze image that are stored on EXAMION X-AQS PACS server.

All acquired image data is preserved in the format in which it is received. Changes may be made to the presentation of the image. These changes are saved as a display definition (Presentation states) only and do not alter the acquired image pixel data. All display definitions can be reversed to the original state at any time System interfaces The EXAMION X-AQS software acts in two different ways based on the application. Firstly, as EXAMION X-AQS PACS system involves the interaction between various input devices like RIS work station, diagnostic station (or monitors) or Twain scanner documentation, US grabber, Digitizer CR and DR or any DICOM device and output device. Secondly as a standalone acquisition station which receives images from 3rd party RIS work station and sends to 3rd party PACS systems. The following block diagrams showing the major components of the larger system and interconnections that may be helpful to understand the Examion X-AQS in detail

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

The Examion X-AQS™ software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the 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. The Examion X-AQS™ system is compatible with the DICOM 3.x communications standard. It can transfer images processed in PACS and print images with a film printer compatible with DICOM 3.x by using DICOM and network systems.

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

Contraindications: Examion X-AQS™ is not intended for creation of fluoroscopic/ radioscopic, or angiographic images.

The main functions of the Examion X-AQS™ system are:

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 stored (archived) images.

d) Image processing for enhancement of archived images.
e) Review of stored images.
f) Editing of images.
g) DICOM conformance (e.g. DICOM Storage, DICOM Work list, DICOM Print, etc.)
h) For a DR system (X-ray machine and generator and Digital X-ray detector, etc.) or a need to interface with installed X-ray system, the:
   - Ability to configure X-ray exposure condition (kVp, mA, Sec etc.) for various body parts and positions.
   - Communication between Generator Console and Examion X-AQS™.

The X-ray generator control function depends on the X-ray Generator company. The X-ray generator is not part of the Examion X-AQS™ system since the Examion X-AQS™ system can only interface and control the Generator by the algorithm provided by the X-ray Company. The Examion X-AQS™ system can only select or change values of X-ray exposure parameters (kVp, mA second or kVp mAs) according to the defined value determined by each X-ray company.

The Examion X-AQS™ system does not control exposure and electrical charge and calibration X-ray. If the X-ray generator does not allow interfacing with external software the Examion X-AQS™ software cannot be interfaced with X-ray Generator.

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

EXAMION X-AQS™ device is a software product that acquires, handles, displays and manages 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. The general features and functions of the device are:

Feature/Function	Predicate Device	Subject Device	Difference if Any
Intended Use	Software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the 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.	Software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the 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.	Substantially the same
Intended user	Radiologist	Radiologist	None
Network	10/100/100 Ethernet	10/100/100 Ethernet	Substantially the same
Monitor	Above 19inch monitor (Above 1280x900)	Minimum display resolution 1024 X 768	Substantially the same

Feature/Function	Predicate Device	Subject Device	Difference if Any
User interaction/input	Mouse, keyboard, touch monitor	Mouse, keyboard, touch monitor	Substantially the same
Import / export images	Yes	Yes	Substantially the same
Acquisition devices	Computed radiography Digital X-Ray detector	DR	Slight difference. Subject device only uses Digital X-Ray detectors to acquire images,
Imaging interfaces	Yes	Yes	Substantially the same
Image organization	Yes. Patient ID, Name, study instance UDI	Yes	Substantially the same
Image search available	Yes	Yes	Substantially the same
Image storage	Yes	Yes	Substantially the same
Image viewing	Yes	Yes	Substantially the same
Image measurement	Yes	Yes	Substantially the same
Image annotation	Yes	Yes	Substantially the same
Image operations	Yes	Yes	Substantially the same
Security	Yes	Yes	Substantially the same
DICOM 3.0 compatibility	Yes	Yes	Substantially the same
Generator Control	Yes	Yes	Substantially the same
Generator Control Protocol	Yes	Yes	Substantially the same
RAW Image data processing	Yes	Yes	Substantially the same
Post image data processing	Yes	Yes	Substantially the same
Worklist	Yes	Yes	Substantially the same
Patient size/Laterality	Yes	Yes	Substantially the same
Display radiographic technique, kV, mA, ms, mAs	Yes	Yes	Substantially the same
Thumbnail viewing	Yes	Yes	Substantially the same

Feature/Function	Predicate Device	Subject Device	Difference if Any
Login	Yes	Yes	Substantially the same
New patient manual register	Yes	Yes	Substantially the same
X-Ray generator window	Yes	Yes	Substantially the same
Bucky selection	Yes	Yes	Substantially the same
Body part	Yes	Yes	Substantially the same
Generator status display	Yes	Yes	Substantially the same
Image reset	Yes	Yes	Substantially the same
panning	Yes	Yes	Substantially the same
Magnify glass	Yes	Yes	Substantially the same
Fit image	Yes	Yes	Substantially the same
Stitching	Yes	Yes	Substantially the same
Series/Image list	Yes	Yes	Substantially the same

Testing

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 EXAMION X-AQS™ performs all required actions according to the functional requirements specified in the Software Requirements Specification 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 for EXAMION X-AQS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. EXAMION X-AQS™ 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”.