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

MEDIEN INTERNATIONAL Co., Ltd.
% Daniel Kamm, PE
Kamm and Associates
8870 Ravello Ct.
NAPLES FL 34114

October 13, 2017

Re: K172435
Trade/Device Name: Galaxy R Digital Radiography Upgrade
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 07, 2017
Received: August 11, 2017

Dear Mr. Kamm:

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)*
K172435

Device Name
Galaxy R Digital Radiography Upgrade

Indications for Use *(Describe)*
The Galaxy R Digital Radiography Upgrade is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in all general purpose diagnostic procedures. Not for mammography.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K172435

1. Submitter:

Name – **MEDIEN INTERNATIONAL Co., Ltd.**
Address – Medien Office Tower, 50, Heungan-daero 427 Beon-gil Dongan-gu
Anyang-si, KOREA, REPUBLIC OF 435-040
Tel - +82-31-451-9466
Fax - +82-31-451-9468
Contact – Jaehyun Lee, jhlee@medien.co.kr
Date prepared: October 3, 2017

2. Identification of the Device: **Galaxy R Digital Radiography Upgrade**
Classification Name: Stationary x-ray system
Product Code: MQB
Common/Usual Name: Stationary x-ray system (digital)
Device Class/Regulation Number: Class II per 21 CFR 892.1680

3. Predicate Device: Manufacturer: Atlaim
Device: Atal 8C
Number: K113812
Classification Name: Stationary x-ray system
Product Code: MQB
Common/Usual Name: Stationary x-ray system (digital)
Device Class/Regulation Number: Class II per 21 CFR 892.1680

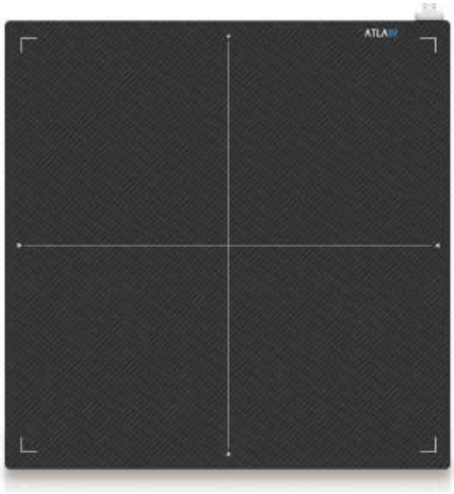
4. A description of the device: This device is medical image acquisition device. X-rays generated by X-ray generator/ tube that penetrate patient's body are converted to a digital file by the detector. After that the detector sends this digital file to a personal computer (via Ethernet) where the companion software has been installed. This software was cleared in our previous submission, K132921, and it has not been modified. A monitor displays this image. Images can then be transferred via the DICOM protocol. There are four models available, two are 14" x 17" and two are 17" x 17" (Available in either CSI or GOS scintillator versions). The user must supply the x-ray generator and tubestand to form a full system. Exposure can be Generator Synchronous, or via - AED (Auto Exposure Detection). The technology is Amorphous Silicon (a-Si) Photodiode coupled with either the Gadox or Cesium Iodide scintillators, same as in the predicate.

5. Intended use of the device: The Galaxy R Digital Radiography Upgrade is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in all general purpose diagnostic procedures. Not for mammography.

6. The Galaxy R Digital Radiography Upgrade has essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device. See the comparison table below.

Comparison Table

Characteristic	Atlaim ATAL 8C, K113812	Galaxy R Digital Radiography Upgrade
Indications	The ATAL 8 and ATAL 8C are indicated for use in general radiographic Intended use: images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications	The Galaxy R Digital Radiography Upgrade is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in all general purpose diagnostic procedures. Not for mammography. (SAME)
Panel Communi-cation	Tethered Gigabit Ethernet, one panel	SAME
Sensor Type	a-Si TFT array Panel detector	a-Si TFT array Panel detector SAME
Scintillator	CSI & GOS	CSI & GOS SAME
Panel Resolution	3072 x 3072 pixels 3.1 lp/mm.	3,072 x 3,072 pixels 3.7lp/mm. SAME. Also available in 3072x2560 pixels (14 x 17 size)
Panel Size	17 X 17	17 X 17 SAME or available in 14 x 17
Weight	3.8kg	3.3 kg or 2.9kg (14 x 17) NOT A MEANINGFUL DIFFERENCE
Pixel Size	139 µm	140 µm. NOT A MEANINGFUL DIFFERENCE
Image depth	16 bits	16 bits SAME
Preview Image	2-5 seconds	Less than 3 seconds EQUIVALENT
DICOM	Yes	SAME
Safety/EMC	EN/IEC 60601-1, Safety EN/IEC 60601-1-2 EMC	SAME, plus tested to IEC 60601-1-6, Medical electrical equipment, Part 1-6: General requirements for safety- Collateral Standard: Usability, including IEC 62366: Application of usability engineering to medical devices
Operating Environment	10°-35°C, 20%-75% RH (non-condensing)	Sensor unit: 10-35°C, 40-80% RH(non-condensing) EQUIVALENT
MTF @2 lp/mm	28% CSI, 22% GOS	25% CSI, 20% GOS
Trigger	Auto sense or manual	SAME
Power Source	100 -250V ~ 50/60Hz 250V ~	100 -250V ~ 50/60Hz 250V SAME

Characteristic	Atlaim ATAL 8C, K113812	Galaxy R Digital Radiography Upgrade
Photo		

Comparison Conclusion:

The proposed new device has these similarities:
Similarity of Intended for use, Similarity of Sensor Type, Similarity of Active Area, Similarity of Sensor Pixel, Similarity of Pixel Size, Similarity of Dimensions, and Similarity of Performance characteristics. The minor differences do not have a material effect on safety or effectiveness, and are therefore substantially equivalent.

7. Description of non-clinical tests. The unit has undergone electrical safety and electromagnetic compatibility testing, as well as software validation and risk analysis. Bench testing for imaging characteristics such as MTF and DQE was performed in accordance with the FDA Guidance Document on Solid State Imaging Devices. Labeling complies with FDA guidelines.
   Testing was performed in accordance with the following standards:
   (1) IEC 60601-1, Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
   (2) EN/IEC 60601-1-2:2007, Medical electrical equipment Electromagnetic Compatibility
   (3) NEMA PS 3.1~PS 3.18 Digital Imaging and Communications in Medicine (DICOM)]
   (4) IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

8. Description of clinical tests. Clinical images of actual patients were submitted; these images were not necessary to establish substantial equivalence based on the modifications to the device (note X-ray digital detector based on imaging technology identical to the predicate image plate) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended. They were evaluated by Board Certified Radiologist and found to be of excellent diagnostic quality.

9. Conclusions drawn: The nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 3, above.