510(k) Summary K132921

JAN 17 2014

1. Submitter:
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Date prepared: December 6, 2013

2. Identification of the Device: Galaxy Plus Digital Radiography System
Classification Name: Stationary x-ray system ;
Common/Usual Name: Stationary x-ray system (digital)
Regulation Number: 21 CFR 892.1680
Product Codes: MQB and KPR

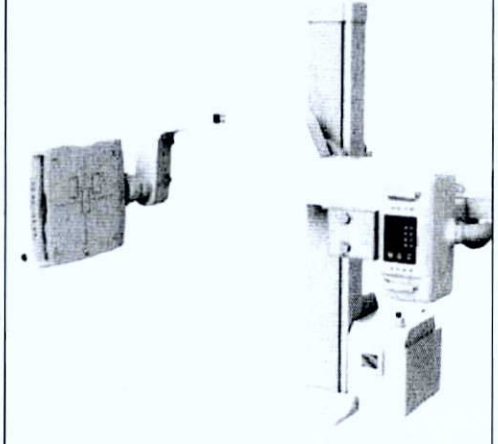
3. Predicate Device: Manufacturer: DRGEM Corporation , Device: DIAMOND-5A, 6A, 8A, 510(k) Number: K102408

4. A description of the device: The digital diagnostic x-ray system consists of a generator, a tube, an x-ray console, a beam limiting device, an image receptor, a u-arm stand and software. The digital panels supplied are intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications. Product features: This system is designed to maintain the alignment between a tube and the image receptor, regardless of the angle on the image receptor or image tilt positions. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on patients. Its flexibility makes the system ideal for all patient examinations including the standing, sitting and lying patient positions.

5. Intended use of the device: The Galaxy Plus Digital Radiography System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

6. The Galaxy Plus has essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device. See the comparison table below. The differences between the Galaxy and the predicate device are: The Galaxy is available in both straight and U-Arm configurations, the predicate is only U-Arm. The Galaxy generators are available on 40 and 50 kW High Frequency versions, and the predicate generators are available in 52, 68, and 82 kW versions. Four digital panels are available. Two of them are the same panels as employed by the predicate DRGEM in K102408, and the other two panels were cleared by Sedecal in K130883. The software employed is our software that was previously cleared in K093816, but updated. We employ high frequency generator technology, the same generator technology as used in the predicate device.

Comparison Table

Characteristic	Predicate Device: DRGEM Corporation Device: DIAMOND-5A, 6A, 8A 510(k) Number: K102408	Galaxy Plus Digital Radiography System K132921
Indications	The DIAMOND-5A,6A,8A Digital Diagnostic X-ray System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.	The Galaxy Plus Digital Radiography System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.
Digital Receptor Panel	Atlaim Atal 8 or Atal 8C	Galaxy F or Galaxy FC (Atal 8 or Atal 8C as cleared in K113812) or Toshiba FDX4343R, FDX3543RP, as cleared in K130883.
Panel Communication	Tethered Ethernet, one panel	Same
Panel Resolution	9.4 megapixel	Galaxy F or Galaxy FC (Atal 8 or Atal 8C as cleared in K113812): 9.4 megapixel Toshiba FDX4343R, FDX3543RP, as cleared in K130883.: 9.4 megapixel for 17 x 17, 7.5 megapixel for 14 x 17.
Panel Size	17 X 17	17 X 17 or 14 X 17
Pixel Size	139 µm	143 µm Toshiba 139 µm Galaxy (Atal)
DICOM	Yes, Via Panel	SAME
Tube Stand	C-Arm	SAME
Generator	"GXR" 52, 68, and 82 kW	"CMP 200": 40, 50kW
Safety	EN/IEC 60601-1, (2006) EN/IEC 60601-1-2 (2007)	SAME
Photo		Available in two configurations: 

7. Description of non-clinical tests. The unit has undergone electrical safety and electromagnetic compatibility testing, as well as software validation and risk analysis. Biocompatibility testing was performed in accordance with applicable ISO standards. Test reports were submitted for the following standards:
EN/IEC 60601-1: 2006 Electrical Safety Testing for the Stand .
EN/IEC 60601-1: 2006 Electrical Safety Testing for the System
EN/IEC 60601-1-3 Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
EN/IEC 60601-2-28 Medical electrical equipment Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
EN/IEC 60 601-2-54 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
EMC System Test Results: IEC 60601-1-2:2007, EN/IEC 60601-1-2:2007 CISPR 11:2009/A1:2010 IEC 61000-3-2:2005/A1 :2008/A2:2009 IEC 61000-3-3:2008. In addition a CSA(US) certification was provided for the generator. Non-clinical performance tests were provided by the respective panel manufacturers.

8. Description of clinical tests. Clinical images for all four panels were obtained in accordance with the FDA Guidance Document on Solid State Imaging Devices. They were evaluated by board certified radiologist and found to be of good 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.

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

January 17, 2014

Medien International Co., Ltd.
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K132921
Trade/Device Name: Galaxy Plus
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, KPR
Dated: December 12, 2013
Received: December 16, 2013

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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): K132921

Device Name: Galaxy Plus Digital Radiography System

Indications for Use:
The Galaxy Plus Digital Radiography System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

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

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

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

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