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

March 4, 2016

Apelem-DMS Group
% Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
200 Homer Avenue
ASHLAND MA 01721

Re: K160301
Trade/Device Name: Platinum dRF Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: February 1, 2016
Received: February 4, 2016

Dear Dr. Orton:

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)*
K160301

Device Name
Platinum dRF Imaging System

Indications for Use *(Describe)*

The Platinum dRF Imaging System is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, diagnostic fluoroscopy, conventional linear tomography, angiography and pediatric examinations.

The Platinum dRF is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, digital angiography and digital subtraction angiography (DSA).

The Platinum dRF may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

The Platinum dRF is not indicated for use in interventional radiology.

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.

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Special 510(k) Summary
as required by 21 CFR 807.92(a)

A) Submitted by: Apelem-DMS Group
Parc Scientifique Georges Besse
175 Allee Von Neumann, 30035 Nimes cedex 1
France

Official Contact: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

B) Common name: System, X-Ray Fluroscopic, Image-Intensified

Proprietary Name: Platinum dRF Imaging System

Device Class: Class II

Regulation and: 21 CFR 892.1650
Product code: JAA

Classification panel: Radiology

C) Predicate: K131766 Apelem-DMS Platinum dRF Imaging System

D) Date Prepared: February 1, 2016

E) Device Description

The Apelem-DMS Platinum dRF Imaging System ("Platinum") is not a stand-alone device, but functions as a platform for FDA cleared or registered components (i.e. generator, panel detector, detector collimator, X-ray tube and software imaging packages), that are installed with a Apelem-DMS manufactured radiological examination table, control panel with system controller software, and electrical panel.

The Platinum dRF remote controlled table is a radiologic table equipped with a flat panel electronic detector. This table is used to perform general digital radiological, fluoroscopy and peripheral angiography. This device allows for treatment on the whole body, using all angles. It allows the user dynamic acquisition for the whole body, to target the zones to analyze, and to be able to track contrast media.

The subject of this Special 510(k) application is the additional offering of the Platinum with a different flat panel detector (RF4343 FL) that does not include some less regularly used options (of the FDA cleared Platinum with RF4343 flat panel detector), has lower frames/sec

and does not include a lead shield. A lead shield for use with the RF4343 FL is manufactured and installed by DMS. This additional offering is less expensive and will fit the needs of most customers.

E) Intended Use/Indications For Use:

Intended Use/Indication for Use: The Platinum dRF Imaging System is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, diagnostic fluoroscopy, conventional linear tomography, angiography and pediatric examinations.

The Platinum dRF is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, digital angiography and digital subtraction angiography (DSA).

The Platinum dRF may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

The Platinum dRF is not indicated for use in interventional radiology.

F) Substantial Equivalence Comparison and Discussion

	Platinum dRF Imaging System K131766 With RF4343	**Platinum dRF Imaging System With RF4343 FL**
Product code	JAA	JAA
Flat detector	4343	4343 FL
Frame rate	12f/sec (RAD) 18f/sec fluoroscopy (large field)	12f/sec (RAD) 13f/sec fluoroscopy (large field)
Image specifications	No change	
Lead shield	Yes; included	No; included in the manufacture of the Platinum by Apelem-DMS
Platinum remote control table	No change	

The Platinum with RF4343 or RF4343 FL flat panel detector is the same device, but offered with different flat panel detectors. There is no change in the Indications for Use. The change in frame rate has no impact on image quality as the image specifications are not changes. Both devices include a protective lead shield. The RF4343 FL flat panel will be integrated into the Platinum manufactured by APELEM and not into another vendor's device.

G) Compliance with Design Controls

The results of assessment under Design Controls supports that the Apelem-DMS Platinum dRF Imaging System with RF434FL flat panel detector is substantially equivalent to the predicate device. The differences between the RF4343 and RF4343 FL flat panel detector do not raise different issues of safety or effectiveness.

Conclusion

The Platinum dRF Imaging System with RF4343 FL flat panel detector has the same intended use, technology, and uses the same components as the predicate device with the exception of the flat panel detector. The Platinum with RF4343 FL has no impact on the image quality or safety of the device, and does not raise different issues of safety or effectiveness. The Platinum dRF Imaging System with RF4343 flat panel detector and the Platinum dRF Imaging System with RF4343 FL flat panel detector are substantially equivalent.

H) Compliance with Consensus Standards

The Platinum dRF Imaging System with flat panel detector RF4343 FL complies with the following standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007: Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests
- IEC 60601-1-3 Ed. 2.1 IEC 60601-1-3 Ed. 2.1: Medical electrical equipment Part 1-3 General requirements for basic safety and essential performance Collateral Standard Radiation protection in diagnostic X ray equipment