Apelem-DMS Group
% Mr. Scott Blood
Senior Regulatory Affairs Consultant
MEDIcept, Inc.
200 Homer Avenue
ASHLAND MA 01721

January 22, 2021

Re: K203010
Trade/Device Name: Platinum dRF Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA
Dated: December 21, 2020
Received: December 28, 2020

Dear Mr. Blood:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203010

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 radiology and diagnostic fluoroscopy examinations, conventional linear tomography and pediatrics 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, cranial, skeletal, thoracic, lung and urogenital tract examinations.

It may also be used in: lymphography, endoscopy, myelography, venography and arthrography.

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

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.

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

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1. 510(K) SUMMARY

K203010

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1. Submitter's Information

Name: Apelem-DMS Group
Address: Parc Scientifique Georges Besse, 175 Allee Von Neumann, 30035 Nimes cedex 1 France

Phone: 33 466 29 09 07

Official FDA Contact:
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Ashland, MA 01721
Scott Blood
sblood@medicept.com
978-729-5978

Date Prepared: November 4th, 2020

1.2. Device Administrative Information

Trade Name:	Platinum dRF Imaging System
Device Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Common Name:	System, X-Ray Fluoroscopic, Image-Intensified
Regulatory Class:	Class II per 21 CFR 892.1650
Product Code:	JAA- 21 CFR 892.1650, Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology

2. LEGALLY MARKETED PREDICATE DEVICE

The following is the identified predicate device:

The predicate referenced below has not been subject to a design-related recall.

Apelem-DMS Group Group – K160301– Platinum dRF Imaging System

- *Indications for Use:*

  Indications for Use for DMS Platinum dRF Imaging System:

  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.

3. DEVICE DESCRIPTION

The subject of this Special 510(k) application is the change to the imaging software system to the ADAM Imaging System. As the resources are now available, Apelem-DMS Group was able to develop their own Imaging System called the ADAM Imaging System. The ADAM Imaging System will now be developed by Apelem-DMS Group. The predicate device (K160301) had an Off the Shelf Software Imaging System called DUET DRF Imaging System which was developed by Thales.

The ADAM Imaging System is a digital image acquisition system to be used in conjunction with a detector during radiography or fluoroscopy X-ray examinations to acquire, display, process and export images according to DICOM protocol via a network connection.

The ADAM Imaging System software interfaces with an X-Ray detector to acquire raw pixel data and image processing algorithms which transform raw pixel data into images and image sequences to help medical professionals with viewing images to for patient diagnosis.

The Duet DRF requires the use of the THALES RF4343 or RF4343 FL detectors, whereas ADAM Imaging System requires the use of the VIEWORKS VIVIX-D 1717G detector. Both detectors employ the same state-of-the-art indirect conversion technology based on CsI scintillator and photo-diodes. The detector Vivix-D 1717G is connected to the x-ray system by cable. The integration with the PLATINUM dRF system has been established and appears adequate. The VIEWWORKS VIVIX-D 1717G detector is only compatible with the ADAM Imaging System.

The Duet DRF and ADAM Imaging System are designed to support general radiography (excluding mammography) and fluoroscopy imaging procedures.

The Apelem-DMS Group ADAM Imaging System is not a stand-alone device. It is integrated into the Platinum dRF Imaging System and 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 Group 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.

3.1. Indications for Use (Proposed Device)

Indications for Use for DMS Platinum dRF Imaging System:

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 radiology and diagnostic fluoroscopy examinations, conventional linear tomography and pediatrics 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, cranial, skeletal, thoracic, lung and urogenital tract examinations.

It may also be used in: lymphography, endoscopy, myelography, venography and arthrography.

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

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

4. SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

	Proposed Device (This Submission): **ADAM Imaging System integrated into the DMS Platinum dRF Imaging System**	**Predicate Device: (K160301)** **Duet Imaging System integrated into the DMS Platinum dRF Imaging System**
FDA Product Code	JAA	JAA
Single Use/Reusable	Reusable	Same
Indications 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 radiology and diagnostic fluoroscopy examinations, conventional linear tomography and pediatrics 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, cranial, skeletal, thoracic, lung and urogenital tract examinations. It may also be used in: lymphography, endoscopy, myelography, venography and arthrography. The Platinum dRF may also be used for outpatient or emergency services, as well as for mobile transport examinations (wheelchair and bed). The Platinum dRF is not indicated for use in interventional radiology.	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,

	Proposed Device (This Submission): ADAM Imaging System integrated into the DMS Platinum dRF Imaging System	Predicate Device: (K160301) Duet Imaging System integrated into the DMS Platinum dRF Imaging System
		as well as for mobile transport (wheelchair and bed) examinations. The Platinum dRF is not indicated for use in interventional radiology.
Use Environment	Hospital or clinical setting by a licensed doctor, orthopedic surgeon, radiologist, radiological technician, or technician authorized by the manufacturer	Same
Patient Contact	The patient does not come into direct contact with the ADAM Imaging System component or the Detector. The patient comes in contact with the examination table only.	Same
Flat Detector	VIEWORKS VIVX-D 1717G	RF4343 FL
Frame Rate	12f/sec (RAD) 18f/sec fluoroscopy (large field), No change	Same
Image Specifications	No Change	Same
Lead Shield	Included	Same
Platinum examination remote control table	No change	Same
Imaging System Component	ADAM Imaging System	Duet DRF Imaging System

	Proposed Device (This Submission): ADAM Imaging System integrated into the DMS Platinum dRF Imaging System	Predicate Device: (K160301) Duet Imaging System integrated into the DMS Platinum dRF Imaging System
Control Panel with System Controller Software	No change	Same
Electrical Panel	No change	Same
Platinum Software	No change	Same

The technological characteristics of the Detector are summarized in the table below:

Detector Information	Proposed: ADAM Imaging System Detector Information	Predicate: Duet Imaging System Detector Information (K160301)	Comment
Manufacturer of detector	VIEWORKS	THALES	Different manufacturers but similar technology
Model Name	VIVIX-D 1717G	PIXIUM RF 4343 FL	Different manufacturers but similar technology
Scintillator	CsI	CsI	Same
Pixel Pitch	140µm	148µm	ADAM Imaging System's detector has a smaller pixel pitch which means better detail detectability

<table>
<tr><th>Detector Information</th><th>Proposed: ADAM Imaging System Detector Information</th><th>Predicate: Duet Imaging System Detector Information (K160301)</th><th>Comment</th></tr>
<tr><td>Pixel Matrix</td><td>3072 x 3072 pixels</td><td>2874 x 2840 pixels</td><td>Adam Imaging System’s detector has a larger pixel matrix which means a larger detection field.</td></tr>
<tr><td>Image Size</td><td>17” x 17”</td><td>17” x 17”</td><td>Same</td></tr>
<tr><td>Grayscale</td><td>16 bits</td><td>16 bit</td><td>Same</td></tr>
<tr><td>Resolution</td><td>3.5 linepairs/mm</td><td>3.4 linepairs/mm</td><td>The performance of both detectors are similar enough (>3%) for the procedures indicated</td></tr>
<tr><td>Modulation Transfer Function (MTF)</td><td>
<table>
<tr><th></th><th>Minimal</th><th>Typical</th></tr>
<tr><td>MTF IEC 0.5 lp/mm</td><td>78 %</td><td>83 %</td></tr>
<tr><td>MTF IEC 1 lp/mm</td><td>50 %</td><td>55 %</td></tr>
<tr><td>MTF IEC 2 lp/mm</td><td>20 %</td><td>25 %</td></tr>
<tr><td>MTF IEC 3 lp/mm</td><td>5 %</td><td>10 %</td></tr>
<tr><td>MTF IEC Nyquist</td><td>-</td><td>-</td></tr>
</table>
</td><td>
<table>
<tr><th></th><th>Minimal</th><th>Typical</th></tr>
<tr><td>MTF IEC 0.5 lp/mm</td><td colspan="2">79%</td></tr>
<tr><td>MTF IEC 1 lp/mm</td><td>55 %</td><td>66 %</td></tr>
<tr><td>MTF IEC 2 lp/mm</td><td>25 %</td><td>35 %</td></tr>
<tr><td>MTF IEC 3 lp/mm</td><td>10 %</td><td>19 %</td></tr>
<tr><td>MTF IEC Nyquist</td><td>7 %</td><td>15 %</td></tr>
</table>
</td><td>Performance of both detectors are sufficient for general radiographic procedures.</td></tr>
<tr><td>Detective Quantum Efficiency (DQE)</td><td>75%
<table>
<tr><th></th><th>Minimal</th><th>Typical</th></tr>
<tr><td>DQE 0.5 lp/mm 2 µGy</td><td>60 %</td><td>65 %</td></tr>
</table>
</td><td>78%
<table>
<tr><th></th><th>Minimal</th><th>Typical</th></tr>
<tr><td>DQE 0 lp/mm 2 µGy</td><td>65 %</td><td>73 %</td></tr>
</table>
</td><td>See Notes below.</td></tr>
</table>

Detector Information	Proposed: ADAM Imaging System Detector Information	Predicate: Duet Imaging System Detector Information (K160301)	Comment
Dimensions	471 x 471 x 35 mm	500 x 490 x 45.5 mm	VIEWORKS detector is smaller than the predicate which will enable easier installation.
Weight	10 kg	9.1kg	VIEWORKS detector is heavier than the predicate but as the difference is less than 1 kg there is no impact.

Notes:

Differences in Detective Quantum Efficiency (DQE):

The predicate device has a DQE of 78% if the shot noise was the only cause to be taken into account, i.e. the proportion of photons that are detected. This is close to the value found for the subject device detector (75%). The difference between the two detector DQE values is low enough to be considered equivalent because:

1. The difference in the required dose to obtain a given image quality is small enough (ratio of 78% to 75%) not to have any clinical significance (<10% of variation)
2. The evaluation of DQE, which combines information about the signal and the noise, has error margins: no definitive conclusion can be given if the difference is <5%
3. The DQE value can vary somewhat between different units of the same model, specially from a small difference in the scintillator thickness. This can be seen from the predicate device detector specification, which indicates 5% of difference between the "minimal" and "typical" values of the DQE.

The image below shows the design of the proposed (Apelem) and predicate (Thales) Imaging Systems.

Manufacturers	APELEM	THALES
Design		

5. COMPLIANCE WITH DESIGN CONTROLS

The results of assessment under Design Controls supports that the Apelem-DMS Group Platinum dRF Imaging System integrated with the ADAM Imaging System component is substantially equivalent to the predicate device. There are no new causes of risk or no new cause of existing risk, therefore the change does not raise different issues of safety or effectiveness.

5.1. Compliance with Standards

The Platinum dRF Imaging System with the ADAM Imaging System component and VIEWORKS detector comply with the following standards:

1. IEC 60601-1:2005/A1:2012 Medical Electrical Equipment: General Requirements for basic safety and essential performance
2. IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
3. IEC 60601-1-3:2008+A1:2013 Medical electrical equipment - part 1-3: general requirements for basic safety and essential performance - collateral standard: radiation protection in diagnostic x-ray equipment.
4. IEC 60601-2-54:2009 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
5. EN ISO 14971:2012 Application of Risk Management to Medical Devices
6. IEC 62304:2006 Medical Device Software – Software life cycle processes
7. EN 1041:2008 Information supplied by the manufacturer of Medical devices
8. EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

6. CONCLUSION

The Apelem-DMS Group Platinum dRF Imaging System integrated with the ADAM Imaging System has the same intended use, technology, materials, and uses the same components as the predicate device except for the ADAM Imaging System component and VIEWORKS Detector. The changes to the proposed device have little to no impact on the safety or performance device (i.e. image quality) and no additional questions regarding safety or effectiveness have been raised. The fundamental scientific technology of the proposed device included in this submission remains unchanged from the legally marketed predicate device. Therefore, the proposed device is substantially equivalent to the predicate device.