DRGEM Corporation
% Mr. Carl Alletto
Consultant
OTech, Inc.
8317 Belew Drive
MCKINNEY TEXAS 75071

February 5, 2019

Re: K183388
Trade/Device Name: JADE Mobile X-Ray
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: December 1, 2018
Received: December 14, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183388

Device Name
JADE Mobile X-Ray

Indications for Use *(Describe)*
The JADE Mobile X-Ray, is a mobile X-ray device, for the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. This device is not intended for mammography, bone density, or dedicated pediatric applications.

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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510(k) Summary of Safety

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

510(k) number: K183388

Date Prepared:

December 1, 2018

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

Mr. Ki-Nam YANG
Director | QM representative
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	JADE Mobile X-Ray
Common Name:	Mobile X-Ray System
Classification	System, X-Ray, Mobile
Regulation Number:	892.1720
Product Code:	IZL
Device Classification:	Class II

Predicate Device: 21 CFR 807. 92(a)(3)

The JADE Mobile X-Ray, device is substantially equivalent to K182317:

Device Classification Name	System, X-Ray, Mobile
510(K) Number	K182317
Device Name	AMADEO M-DR Mini, AMADEO M-AX Mini
Applicant	OEHM UND REHBEIN GMBH
Regulation Number	892.1720
Device Classification	Class II
Classification Product Code	IZL
Subsequent Product Code	MQB
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
Summary	Summary
Type	Traditional

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

The JADE Mobile X-Ray, is a mobile x-ray device that comes in two models: JADE-32 (3.2kw max. output and JADE-40 (4kw max. output). JADE is a non-motorized mobile diagnostic x-ray device that can facilitate X-ray examinations, in situations where it is not possible or

feasible to transport the patient to a ward with fixed equipment. The unit is stable and precise when using the optional Mobile or Portable Stand. The electric tube unit and wheel locks, column rotation, and a simple user interface to provide for added operator convenience and rapid patient positioning. X-Ray technique presets can be saved. The JADE Mobile X-Ray device can be used with a film screen cassette or a flat panel detector which are supplied by the user and are not part of the JADE Mobile X-Ray, device. The software used with the JADE Mobile system is new and is not based on the predicate device.

“Caution” The JADE Mobile X-ray should not be used as a handheld device.

The JADE device consists of:

- High-Frequency X-ray Generator
- Collimator with 30 seconds LED lamp timer
- User Programmable APR
- Exposure Hand Switch
- Software(SDK, HT Frame and Membrane Console Firmware)

No.	PESS	Processor	Description
1	JADE	JADE_HTC	JADE_HTC at HT control board in x-ray generator controls whole x-ray generation process by the control of System Control Module in CPC_SDK. This module controls x-ray parameters such as kV, mA and exposure time, and controls the filament and detector interfacing.
		JADE_MCC	JADE_MCC at console board in control console consist of generator control module. JADE_MCC display the state of X-ray parameter and generator.
2	CPC	CPC_SDK	CPC_SDK is the software provides user interface on generator control. CPC_SDK consists of generator control Module and Display Module, System Diagnosis Module

- Optional equipment:
  - Remote Controller (to control the Collimator Lamp, X-ray Exposure)
  - Portable Stand
  - Mobile Stand

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

The JADE Mobile X-Ray, is a mobile X-ray device, for the purpose of acquiring X-ray images of the desired parts of a patient’s anatomy. This device is not intended for mammography, bone density, or dedicated pediatric applications.

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

- JADE Mobile X-ray specifications are in TABLE 1.
- TABLE 2 is the collimator specifications and
- TABLE 3, compares the predicate device and the new device. Any differences between the predicate and the new device has no impact on safety or efficacy of the new device and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

TABLE 1 Mobile X-Ray Unit Specs

510(k) Summary of Safety

Model	JADE-32	JADE-40
Input Power	100 – 240V~ (Free voltage input), 50/60Hz	110 – 240V~ (Free voltage input), 50/60Hz
Output Rating	Max. 3.2 kW (40mA@80kV, 32mA@100kV, 25mA@120kV)	Max. 4 kW (50mA@80kV, 40mA@100kV, 32mA@120kV)
Type	Microprocessor controlled High Frequency inverter	
KV Range	40 ~ 120 KV, 81Step (1KV Step)	
mA Range	10 ~ 80 mA, 10Step (10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80mA)	10 ~ 100 mA, 11Step (10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100mA)
Exposure Time	0.01 ~ 10 seconds, 21Step (in 25% Steps)	
mAs Range	0.1 ~ 250 mAs, 35Step (in 25% Steps)	
X-ray Tube Type	Stationary Anode	
Focal Spot Size (Small / Large)	0.5 / 1.5 mm	
Anode Heat Storage Capacity	56,000HU (40,000 J)	
Power Cord Length	5 m	
Exposure Hand-switch Cord Length	5 m (Max. Length)	
X-ray switching frequency	100 kHz	
Control	2 Point Control (kV, mAs)	
Control Display	LED (7-seg display & indicators)	
Anatomical Programs	Preprogrammed 9 APR data – User Programmable	
External Interface	USB, Bluetooth (Option), DR Interface (Option)	
Max. Input Power Rating	25 A @ 240 V~, 35 A @ 100 V~	24 A @ 240 V~, 34 A @ 110 V~
Weight	16.8kg (37lb) (Including Collimator)	

TABLE 2 - Collimator Specs

Model	KM1
Manufacturer	DRGEM
Control	Manual with 15, 30, 45, 60sec. Lamp timer
Field Shape	Rectangular
Max. Field Size	44x44cm (at 100cm SID)
Leakage Radiation	< 40mR/hr. (at SID 1m)
Max. kVp shield	150kV
Inherent Filtration	2.0mmAl eq.
Luminosity	Over 160LUX at 100cm SID
Light source	19W LED
Standard	Rotating flange
Option	Tape measure (Max. 200cm)
Electrical Rating	12 – 45VDC, 20W

Dimension / Weight	172(W) x 172(D) x 97(H) mm / 2.5kg(5.5lb)

TABLE 3 – Predicate and Subject Device Comparison

The following information compares the subject device to the predicate. Any differences are due between the subject device and the predicated device has no impact on safety or efficacy of the modified device and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed device.

Characteristic	Subject Device	Predicate K182317, AMADEO M-DR Mini, AMADEO M-AX Mini
Indications for Use	The JADE Mobile X-Ray, is a mobile X-ray device, for the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. This device is not intended for mammography, bone density, or dedicated pediatric applications.	They Portable Diagnostic Radiographic System are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography).
Configuration	Same as predicate	Line operated portable
Generator	High frequency made by DRGEM	High frequency made by POSKOM
Generator power	Two power levels: JADE-32 (3.2kw max. output and JADE-40 (4kw max. output).	One power level: 5 KW
Peak Voltage	120kv	110kv
Collimator	DRGEM Corporation (Model KM1)	POSKOM PCMAX-100CAH

510(k) Summary of Safety

Characteristic	Subject Device	Predicate K182317, AMADEO M-DR Mini, AMADEO M-AX Mini
Image acquisition	None	None or Either the PerkinElmer XRpad2 4336 detector as cleared in K161966 or the XenOR 35CW (CareRay CareView1500CW) cleared in K150929 (our model XenOR 35CW)
Software	DRGEM SDK	DICOMPACS DX-R
Connections	USB, RS232 or Wi-Fi	Ethernet or Wi-Fi
DICOM	None	Yes
Electrical Safety	Same	Electrical Safety per IEC-60601. EMC per IEC-60601-1-2; IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment IEC 60601-2-54 Particular Requirements for The Basic Safety And Essential Performance of X-Ray Equipment for Radiography and Radioscopy
		

Clinical Testing:

Clinical testing is not necessary for the JADE Mobile system in order to demonstrate substantial equivalence to the predicate device.

Nonclinical Testing:

The complete system has been assessed and tested at the factory and by Standards testing facilities. The JADE Mobile X-Ray, device has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by JADE, and followed the process documented in the System Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

The main components of JADE Mobile X-ray, comply with the applicable regulatory requirements and design standards as follows:

1) SAFETY

- IEC/EN 60601-1 3.1 Edition

- EN 60601-1:2006/A1:2013 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- EN 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
- EN 60601-1-6:2010/A1:2015, Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 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
- EN 60601-2-28:2010, Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

2) EMC

- EN60601-1-2:2015, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN55011:2009/A1:2010, CISPR 11 :2009/A1:2010
- EN 61000-3-2:2014, Electromagnetic compatibility (EMC) -- Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16 A per phase)
- EN61000-4-2:2009, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- EN61000-4-3:2006/A1:2007/A2:2010, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- EN61000-4-4:2012, Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
- EN61000-4-5:201, Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
- EN61000-4-6:2014, Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
- EN61000-4-8:2010, Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- EN61000-4-11:2004, Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests

4) OTHERS

- 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 (ISO 15223-1:2016)
- IEC TR60878:2003, Graphical Symbols for electrical equipment in medical practice
- IEC60417-1:2000, Graphical Symbols for use on equipment-part1 : overview and application
- ISO 14971: 2012, Medical devices - Application of risk management to medical devices (ISO 14971:2012)

The 510(k) Pre-Market Notification for the JADE Mobile X-Ray, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the voluntary standard survey. The subject device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and

intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, the JADE Mobile X-Ray, device, is substantially equivalent to the predicate device.