Oehm Und Rehbein Gmbh
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FL 34114

September 24, 2018

Re: K182317
Trade/Device Name: AMADEO M-DR mini, AMADEO M-AX mini
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: August 17, 2018
Received: August 27, 2018

Dear Daniel 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. 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 A. 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)*
K182317

Device Name
Amadeo M-DR mini; Amadeo M-AX mini

Indications for Use *(Describe)*
These Portable Diagnostic Radiographic Systems 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).

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."*

Oehm und Rehbein GmbH
Neptunallee 7c
18057 Rostock GERMANY
Phone: (49) 381 36 600 500
Fax: (49) 381 36 600 555
Date Prepared: September 21, 2018
Prepared by: Franziska Günther
Email: franziska.guenther@or-technology.com
510(k) Summary for K182317

1. **Identification of the Device:**
   Trade/Device Names: Amadeo M-DR mini; Amadeo M-AX mini
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL and MQB
   Common/Usual Name: Mobile Diagnostic X-Ray System

2. **Equivalent legally marketed device: K173299**
   Trade/Device Name: DRAGON X SPSL4HC; DRAGON X SPSL8HC
   Manufacturer: Sedecal SA
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL and MQB
   Common/Usual Name: Mobile Diagnostic X-Ray System

3. **Reference legally marketed devices (Digital Panels) K161966 OR K150929**
   Trade/Device Names: XRpad2 4336 HWC-M OR CareView 1500CW
   Manufacturer: PerkinElmer, Inc. OR Careray Digital Medical System CO., LTD.
   Regulation Number: 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Code: MQB
   Common/Usual Name: Digital X-Ray Receptor Panel

4. **Indications for Use (intended use)** These Portable Diagnostic Radiographic Systems 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).

5. **Description of the Device**: The AMADEO M-DR mini Portable X-Ray is a fully digital X-ray system for use for first aid services, intensive care units, emergency departments, as well as ships and mobile hospitals (e.g. container solutions) in inaccessible areas, in laboratories and scientific stations in remote parts of the world. The AMADEO M-DR mini is used for wireless digital X-ray imaging. The device represents the straightforward combination of 510(k) exempt devices (x-ray generator, code

IZO and collimator, code IZX) and already cleared digital panels and imaging software.
Two different models of digital image acquisition panels are offered: PerkinElmer XRpad2 4336 or CareView 1500CW. Both of the panels and the associated software have been previously cleared by FDA (K161966 or K150929). Integration with the portable system was straightforward. The device complies with the US Federal Safety Performance Standard and was safety tested by MET Labs. The key differences between the new device and the predicate device are as follows: Manufacturer of the generator and the digital panels and the accompanying software are different. The similarities and differences are compared in the Substantial Equivalence Chart below.

6. **Safety and Effectiveness, comparison to predicate device.** Bench, test laboratory results, and risk management evaluations indicate that the new device is as safe and effective as the predicate devices. All digital panels have previous FDA clearance and are provided unmodified**.**

7. **Substantial Equivalence Chart**

| **Characteristic** | **SEDECAL DRAGON X SPSL4HC; DRAGON X SPSL8HC K173299** | **Amadeo M-DR mini; (with digital imaging)**<br>**Amadeo M-AX mini (without digital imaging)** |
|---|---|---|
| Intended Use: | These Portable Diagnostic Radiographic Systems 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). | SAME |
| Configuration | Line operated portable | SAME |
| Performance Standard | 21 CFR 1020.30 | SAME |
| Generator | High frequency made by Sedecal | High frequency made by POSKOM |
| Generator power level | Two available power levels:<br>4 KW, 8 KW | One power level: 5 KW |
| Peak voltage | 125 kV | 110 kV |
| Collimator | Ralco R72S | POSKOM PCMAX-100CAH |
| Image acquisition | Toshiba FDX3543RP or FDX3543RPW as cleared in K130883 | Either the PerkinElmer XRpad2 4336 detector as cleared in K161966 or the XenOR 35CW (CareRay CareView1500CW) cleared in K150929 (our model XenOR 35CW) |

| **Characteristic** | **SEDECAL DRAGON X SPSL4HC; DRAGON X SPSL8HC K173299** | **Amadeo M-DR mini; (with digital imaging)**<br>**Amadeo M-AX mini (without digital imaging)** |
|---|---|---|
| Digital Panel Specifications | FDX3543RP: 143 µ 2448 ×2984 pixels or:<br>FDX3543RPW: 140 µ, 2466 ×3040 pixels | XRpad2 4336: 100 µ, 3524 × 4288 pixels or:<br>XenOR 35CW (CareView1500CW): 154 µ 2304 x 2816 pixels |
| Software | eCom software as cleared in K130883 | DICOMPACS DX-R |
| Connection | Ethernet or Wi-Fi | SAME |
| DICOM | YES | YES |
| Power Source | AC Line | SAME |
| Electrical safety and EMC | Electrical Safety per IEC-60601. UL listed; EMC per IEC-60601-1-2;<br>IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment<br>IEC 60601-2-54 Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy | SAME (MET Listed) |
| Standards (Other than Electrical and EMC) | Wi-Fi 802.11b/g and:<br>FCC Rules and Regulations 47 CFR Chapter I Part 15 Subpart B; Part 18 Subpart C ICES-003 ISSUE 5 (2012) & ICES-001 ISSUE 4 (2014) & ANSI C63.4-2009.; US PERFORMANCE STANDARD FOR X-RAY | SAME |
| Photos |  |  |

8. Summary of Laboratory Testing and Bench Testing: Laboratory testing included performance testing to the DHHS Radiation Safety Performance Standard, 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, and FCC Parts 15 and 18. A risk analysis was performed. Test images were obtained to confirm total system functionality. Every unit manufactured undergoes thorough performance testing which includes visual and configuration testing, leakage testing, hi-pot testing, generator testing, including generator controls (voltage, current, timing), and image acquisition.

9. Summary of Clinical Testing: Not required because the proposed digital panels have prior FDA clearance.

10. Conclusion After analyzing bench and laboratory testing to applicable standards, it is the conclusion of Oehm und Rehbein GmbH that the new AMADEO M-DR Portable X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.