June 19, 2020

VMI Tecnologias LTDA
% Mr Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K201340
Trade/Device Name: AQUILA 320 D / AQUILA 320 S
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: May 15, 2020
Received: May 20, 2020

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. 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,

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)*
K201340

Device Name
AQUILA 320 D / AQUILA 320 S

Indications for Use *(Describe)*
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.

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K201340

510(k) Summary: 510(k) Number K201340

VMI Tecnologias LTDA
Rua Prefeito Elizeu Alves Da Silva, 400 –
Dist. Ind. Genesco Aparecido De Oliveira,
Lagoa Santa, Minas Gerais, Brazil
Date Prepared: June 17, 2020
Contact: Otavio Viegas
Tel: +55 (31) 3370-3750

1) **Identification of the Device:**
Trade/Device Name: AQUILA 320 D / AQUILA 320 S
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Codes: IZL, MQB.
Common/Usual Name: Digital Mobile Diagnostic X-Ray System

2) **Equivalent legally marketed device**: **K161345, Sedecal SA**
Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Codes: IZL, MQB.
Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3) **Reference devices:** We employ these cleared devices without modification:
Digital Image Detector - DRTECH EVS 4343: K162555
Digital Image Detector - DRTECH EVS 3643: K162555
Digital Image Detector - CareRay model CareView 1500CW: K150929
Digital Image Detector - CareRay model CareView 1800CW: K172581
Digital Image Detector - CareRay model CareView 750CW: K163019
Digital Image Detector - CareRay model CareView 1500C/L: K153058
Digital Image Detector - CareRay model CareView 1800L: K153492
Digital Image Detector - CareRay model CareView 750C: K163019

Regulation Number: 21 CFR 892. 1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB

4) **Indications for Use:** 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**: Aquila 320-D Series: Small, light, easy handling. High Performance, High Power 320 mA, Leading Technology. Capacitive discharge technology, wireless image capture and transmission technology, smartphone image access. Wireless Detector and Workstation on touchscreen notebook or tablet.
   High frequency generator with micro-processor controls: Power 35.2 KW (The Aquila 320-S comes without the digital panels and workstation)
   a) Single phase/biphasic power supply
   b) 110/115/127/220/230 VCA-50/60 Hz according to customer request.
   c) Resonant technology: IGBT's switching
   d) Storage System by capacitive Bank, powered by simple 3- pin socket: 2 kVA's
   e) KV Range: 40 to 125 kV
   f) mA range: 20 to 320 mA (Automatic focus selection)
   g) mAs range: 0.08 to 320 mAs (above 320 but optional)
   h) Exposure time: 0.004 to 5 sec.
   i) Anatomical program of organs: 272 pre-programmed techniques
   j) Numerical indication in kHU's of X-ray tube heating on the control panel
   k) Specific commands for preparation and X-ray shooting
   l) Intelligent anode braking by software, preserving the life span of the X-ray tube
   m) Main protections:
      i) -Thermal protection of the X-ray emitter Assembly (overheating)
      ii) -Failure in the filament circuit of sub and over current;
      iii) -Failure of the rotary circuit of sub on current;
      iv) -exposure time above allowed;
      v) -Overload protection system in X-ray tube
   n) Flat Panel Detectors: (All FDA Cleared)
      i) Digital Detectors with cesium iodide scintillator (CsI) and amorphous silicon converter (A-SI) - (optional: amorphous selenium a-Se).
      ii) Active Area: 43x43cm, 35x43cm or 24x30cm.
      iii) Technology: Wireless.
      iv) Charger for two simultaneous batteries.
      v) Two batteries or more (optional).
      vi) Image resolution with matrix: 2048 × 2560 pixels or larger (optional)
      vii) Pixel size: 120 µm or larger,
      viii) A/D converter: 14 bits or higher.
      ix) Preview after X-ray shooting in 2 seconds and image formation in 7 seconds
      x) Protective Case for detector (optional).
   o) Workstation:
      i) Touchscreen Notebook or Tablet Surface
      ii) Processor: Core i5 or higher (optional).
      iii) Hard drive SSD: 256 GB capacity or higher (optional).
      iv) RAM: 4 GB or larger (optional).
      v) Storage Capacity: 15,000 images or larger (optional).
      vi) Indication, on the home screen, of the connection status with PACS and Dicom printer.
      vii) Inserting patient data manually, via Worklist server.
      viii) Emergency exams, without the need for patient registration.
      ix) Insertion of linear measurements and angulations.
      x) Localized zoom application. Full zoom application in the image.
      xi) Brightness/contrast application.
      xii) Zoom tools, adjust to window size, mirroring, and
      xiii) brightness/contrast adjustment at the time of printing.
      xiv) Image rotation and inversion, possibility of inserting fixed/edited text.

xv) Export of the list of exams performed in EXCEL spreadsheet format.
xvi) Image mirroring tools in the vertical and horizontal directions.
xvii) Rotating images of 90 degrees step by step, right and/or left.
xviii) DICOM 3.0 Complete Package with: print (DICOM print), Storage (sending images in DICOM standard for PACS systems, sending to remote report), Modality worklist (dicom working list).

6) Substantial Equivalence Chart

Characteristic	Predicate: K161345, Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR	AQUILA 320 D / AQUILA 320 S
Indications for Use:	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	Mobile System with digital x-ray panel and image acquisition computer	SAME
X-ray Generator(s)	kW Rating: 40 kW only. kV range: From 40 kV to 150 kV in 1 kV steps mA range: From 10 mA to 500 mA	kW Rating: 35.2 kW only. kV range: From 40 to 125 kV in 1 kV steps mA range: From 20 to 320 mA Similar ratings, lower power. But same range of exams can be made. See note below.
Collimator	Ralco R221 DHHS	Choice of Models Leadmec Collimator – LDM206 Ralco Collimator – R104 Ralco Collimator – R104/A Ralco Collimator – R108 SM Collimator – 38A All collimators meet the US Performance Standard
Digital X-ray Panel Supplied	Canon CXDI 401C Wireless (CSI) K133693 Pixel size: 125 µm 3320 × 3408 pixels Canon CXDI 701C Wireless (CSI) K131106 Pixel size: 125 µm 2800 × 3408 pixels Canon CXDI 801C Wireless (CSI) K131106 Pixel size: 125 µm 2800 × 2192 pixels	Wider range of sizes, customer choses a cleared panel from the reference list, above, paragraph number 5. Pixel pitches from 120 to 154µm.
Software	Canon control software CXDI-NE	DROC Software for Careray Detectors, (K201058 and others) ECONSOLE Software for DRTECH Detectors. K152172
Panel Interface	Ethernet or Wi-Fi wireless	SAME
Meets US Performance Standard	YES 21 CFR 1020.30 and 1020.31	SAME. This device complies with all applicable requirements of 21 CFR 1020.30, and 1020.31

Characteristic	Predicate: K161345, Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR	AQUILA 320 D / AQUILA 320 S
Power Source	100 / 110 / 120 /, 127 / 220 / 230 / 240 V~ AC and Batteries	110/115/127/220/230 VCA-50/60 Hz and Batteries SAME
Photos	RadPRO® Mobile  Arm shown retracted	AQUILA 320 D / AQUILA 320 S  Similar appearance and footprint

7) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new devices are as safe and effective as the predicate devices. Proper system operation is fully verified upon installation. We verified that the modified combination of components worked properly and produced diagnostic quality images as good as our predicate generator/panel combination. Regarding the power level of the generator compared to the predicate: Our maximum power level is 12% lower than the predicate, however the power offered is more than sufficient to perform chest and other demanding imaging. For example, a typical adult chest x-ray can be done at 100-120 kVp at 4-8 mAs, well within the capability of the generator. Thus the proposed device can perform the same range of exams that the predicate can perform. The OEM manufacturer of the predicate device offers 20 and 32 kW versions of the same device.

8) **Summary of non-clinical testing:** Systems covering all generator/panel combinations were assembled and tested and found to be operating properly. Firmware was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.* Because the system uses Wi-Fi and Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff.* In addition, we reviewed the FDA guidance *Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff* and added a supplement to our user manual. We also reviewed and implemented the recommendations of other FDA source material at the Image Gently website (http://www.imagegently.org/) and the resources in FDA's Pediatric X-ray Imaging webpage (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm)

The digital panel software employed was already reviewed by FDA in the reference submissions list, above. The labeling was reviewed in light of the FDA guidance document: *Radio Frequency Wireless Technology in Medical Devices.*

Some of the available collimator models offer Class 1 or Class 2 line generator lasers as an optional aid to bucky alignment. All of the lasers meet the US Performance Standard for lasers, and corresponding product reports have been filed. Labeling is in accordance with the US Performance Standard. The predicate device has this laser option as well.

This device complies with all applicable requirements of 21 CFR 1020.30, and 1020.31

The AQUILA 320 D / AQUILA 320 S Mobile X-Ray Units have been tested by 3rd party Nationally Recognized Testing Laboratories to be in compliance with the following International Standards:

IEC 60601-1:2005 + AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; (19-4)

IEC 60601-1-2:2010 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests (19-8: 2014)

IEC 60601-1-3:2011 Medical Electrical Equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment; (12-269: 2013)

IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability; (5-89)

IEC 60601-1-9:2014 - Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design (NR)

IEC 60601-2-28:2012 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (12-204)

IEC 60601-2-54:2011 +2016 AM Medical electrical equipment - Part 2- 54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy; (12-296**)**

9) **Summary of clinical testing**: Clinical testing was not required to establish substantial equivalence because all digital x-ray receptor panels have had previous FDA clearance.

10) **Conclusion: After analyzing bench and clinical tests, it is the conclusion of VMI Tecnologias LTDA that the new AQUILA 320 D / AQUILA 320 S Digital Diagnostic Mobile X-Ray Systems are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**