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

December 1, 2020

Re: K202388
Trade/Device Name: Apolo D / Apolo S
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: October 25, 2020
Received: October 28, 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,

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)*
K202388

Device Name
Apolo D / Apolo 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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510(k) Summary: 510(k) Number K202388

VMI Tecnologias LTDA
Rua Prefeito Elizeu Alves Da Silva, 400 –
Dist. Ind. Genesco Aparecido De Oliveira,
Lagoa Santa, Minas Gerais, Brazil
Date Prepared: November 13, 2020
Contact: Otavio Viegas
Tel: (31) 3370-3750

1) **Identification of the Device:**
   Trade/Device Name: Apolo D / Apolo S
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Codes: KPR, MQB.
   Common/Usual Name: Digital Stationary Diagnostic X-Ray System

2) **Equivalent legally marketed device**: **Sedecal, K133782**
   Trade/Device Name: NOVA FA
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Codes: KPR, MQB.
   Common/Usual Name: Digital Stationary 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: K151942
   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**: Model difference: Apolo D includes a cleared digital x-ray receptor panel with one of two cleared software packages. Apolo S does not come with the digital x-ray receptor panel or software. This is a multifunctional fixed X-ray equipment consisting of Examination Table, Bucky Stand, Tube/Bucky Stand, X-ray Source Assembly (Tube/Collimator), High Voltage Generator plus Operating Panel, Conventional Image Receivers and, in specific version, Image System with Flat panel detector and Workstation for image acquisition, processing and visualization. The equipment was developed to perform radiographic examinations of patients in reclining, standing or sitting positions. Six possible tube head configurations are available: FLOOR TO CEILING TUBE STAND, FLOOR MOUNTED TUBE STAND, ROTARY U-ARM mount with integrated film/digital cassette mount, MANUAL

CEILING-MOUNTED TELESCOPIC TUBE STAND, MOTORIZED CEILING-MOUNTED TELESCOPIC TUBE STAND, ROTARY STRAIGHT ARM mount with integrated film/digital cassette mount. The Apolo provides a complete x-ray system with generator, tube head, and collimator. The generator is made by us, VMI, whereas the tube head, collimator, and digital x-ray receptor panels/software are made by other manufacturers. Tube heads are typically Toshiba and collimators are typically Ralco. The Apolo D comes with digital x-ray receptor panels (see the comparison table below) while the Apolo S comes without digital x-ray receptor panels. This system employs without modification software Econsole cleared in K152172. This software has a Moderate level of concern. The reference detectors made by DRTECH can be used with anti-scatter grids.

6) Substantial Equivalence Chart

Characteristic	Predicate: Sedecal NOVA FA, K133782	Apolo D / Apolo 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	Stationary System with digital x-ray panel and image acquisition computer	SAME
Photo (Ceiling Mount)		 Functionally the same. Wall mount straight arm and a “U” mount tube head configurations are also available.
X-ray Generator(s)	Output power: 50 kW, 65 kW, 80 kW. kV Range: from 40 kV to 150 kV, in 1 kV steps. mA Range: from 10 mA to 1000 mA (Depends on the generator and X-ray tube model)	Output Power 50 or 64 kW kV Range: 40 to 150 kV-increments: 1 kv mA Range: Small Focus 20 / 50 / 100 / 160 / 220 mA Large Focus 280 / 400 / 500 / 630 / 800 mA

Characteristic	Predicate: Sedecal NOVA FA, K133782	Apolo D / Apolo S
Collimator	Ralco R225 ACS (Automatic Collimator) Ralco R225 (Manual Collimator)	Choice of Models Leadmec Collimator – LDM206 Ralco Collimator – R104 Ralco Collimator – R104/A Ralco Collimator – R108 All collimators meet the US Performance Standard
Digital X-ray Panel Supplied	CXDI CANON Detector 401C/401G Compact (K103591). CXDI CANON Detector 55C (K091436) CXDI CANON Detector 501 C (K111682)	DRTECH EVS 4343: K162555 DRTECH EVS 3643: K151942
Detector Performance	For the CANON 501C: (Most recent model) DQE 60% at 0 lp/mm MTF 35 % at 2 cy/mm	EVS 4343: DQE 52 % at 1.0 lp/mm MTF 36.6 % at 2.0 lp/mm EVS 3643: DQE 50 % at 1.0 lp/mm MTF 35 % at 2.0 lp/mm (Comparable results because the CANON MTF was taken at 0 lp/mm)
Detector Resolutions	3,320 x 3,408 2,208 x 2,688 2,800 x 3,408	3,072 x 3072 (EVS 4343) 2,560 x 3072 (EVS 3643) Comparable resolutions
Pixel size	125 µ 160 µ 125 µ	All 140 µ
Software	Canon control software CXDI-NE	ECONSOLE Software for DRTECH Detectors. K152172
Panel Interface	Ethernet or Wi-Fi wireless	SAME
DAP	Typically not provided	Always provided with digital and CR equipped systems (VacuDAP)
Meets US Performance Standard	21 CFR 1020.30 Diagnostic x-ray systems and their major components. 21 CFR 1020.31 Radiographic equipment.	SAME
Power Source	AC Line Only	SAME

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 device. Proper system operation is fully verified upon installation. We verified that this new combination of components worked properly and produced diagnostic quality images. Regarding the power level of the generator compared to the predicate: Our maximum power level is 20% lower than the maximum predicate model, however the power offered is more than sufficient to perform chest and other demanding imaging. The proposed device can perform the same range of exams that the predicate can perform. The OEM manufacturer

of the predicate device offers 50 kW, 65 kW, 80 kW versions of the same device. This system employs without modification software ECONSOLE cleared in K152172. This software has a Moderate level of concern.

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 Apolo D / Apolo S Stationary 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 Apolo D / Apolo S Digital Diagnostic Stationary 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.**