Del Medical, Inc.
% Daniel Kamm, P.E.
Kamm and Associates
8870 Ravello Ct.
NAPLES FL 34114

November 20, 2017

Re: K173018
Trade/Device Name: MDR17 Mobile Direct Radiographic System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: September 22, 2017
Received: September 28, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173018

Device Name

MDR17 Mobile Direct Radiographic System

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.

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.

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510(k) Summary: Del Medical, Inc.
MDR17 Mobile Direct Radiographic System K173018

Company: Del Medical, Inc.
241 Covington Dr.
Bloomingdale, IL 60108

Date Prepared: September 22, 2017

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. General Information:

Establishment/Manufacturer/Location of Manufacturing Site:
Del Medical, Inc.
241 Covington Dr.
Bloomingdale, IL 60108
Establishment Registration Number: 1418964

2. Contact Person:

Tony Bavuso
c/o Del Medical, Inc.
241 Covington Dr.
Bloomingdale, IL 60108
Phone: 847-288-7021

3. Device Name and Classification

Trade Name:	MDR17 Mobile Direct Radiographic System
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1720
Device Class:	Class II
Product Code:	IZL
Subsequent Product Code:	MQB

4. Legally Marketed Predicate Device

Trade Name:	RadPRO® Mobile 40kW
Manufacturer:	Sedecal
510(k) #:	K161345
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1720
Device Class:	Class II
Product Code:	IZL
Subsequent Product Code	MQB

5. 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.

6. Device Description: This is a motorized mobile diagnostic x-ray system. The MDR16 Mobile Direct Radiographic System facilitates 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, yet easy to maneuver due to smooth battery-powered motorization. Electric tube unit and wheel locks, 180º column rotation, and a simple user interface provide for add operator convenience and rapid patient positioning. The MDR17 System allows the acquisition of X-ray images on digital panel, CR, or film, by setting techniques based on anatomic area. Technique presets can be customized. Immediate image display after acquisition, and the possibility of immediate transmission to PACS, help minimize workflow time. Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Furthermore, the intended operators of the MDR17 Mobile Direct Radiographic System are health care professionals familiar with and responsible for the x-ray examinations being performed. To minimize electrical, mechanical, and radiation hazards, Del Medical, Inc. adheres to recognized and established industry practice, and all equipment is subject to final performance testing. The digital x-ray panel includes automatic exposure detection. Two different size panels are available: 35 x 43 cm or 24 x 30 cm. The software is compatible with either panel via menu setting.

7. Substantial Equivalence The MDR17 Mobile Direct radiographic x-ray system is substantially equivalent to the commercially available RadPRO® Mobile 40kW radiographic x-ray system with identical indications for use. (See Table below).

Characteristic	**RadPRO® Mobile 40kW; Sedecal. K161345**	**MDR17 Mobile Direct Radiographic System**
Intended 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.	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)
Performance Standard	21 CFR 1020.30	SAME
Configuration	Motorized, battery operated	SAME
Generator	High frequency	High frequency (SAME)
Generator power level	40 kW (One power level)	40 kW (SAME)
kVp Range	40 to 150 kVp	40 to 130 kV in steps of 1 kV

Characteristic	RadPRO® Mobile 40kW; Sedecal. K161345	MDR17 Mobile Direct Radiographic System
mA Range	10 - 500 mA Selectable	70 to 400 mA automatically associated to kV
Exposure Time Range	0.001 - 10 sec	0,001 ÷ 3 sec according to set mAs
mAs Range	0.1 - 500 mAs	0,1 to 320 mAs
Collimator	Ralco R221 DHHS Manual Collimator	Ralco R108 F Manual Collimator
Image acquisition Panels (Both systems use already cleared digital panels)	Canon CXDI 801C Wireless (CSI) K131106 Pixel size: 125 µm 2192 x 2800 pixels	Pixium 3543EZ Portable Wireless (K133534, K142718 and other clearances) Pixel size 148 µm, 2400 x 2880 pixels **or** the Pixium 2430EZ Portable Wireless , Pixel size 148 µm, 1920 x 1560 pixels Compatible with film and CR systems as well.
Software	Canon control software CXDI-NE	DelWorks DR Software K140825
Connection	Wired or Wireless	SAME
DICOM	YES	YES
Power Source	Single Phase Line Regulation from 100 - 240 Vac (+/-10%)	115 or 230 VAC
Electrical safety and EMC	IEC 60601-1 and IEC 60601-1-2	SAME
Standards (Other than Electrical and EMC)	Wi-Fi 802.11b/g and: FCC Rules and Regulations	SAME
Wi-Fi communication with detectors	Wi-Fi antenna system	SAME

Characteristic	RadPRO® Mobile 40kW; Sedecal. K161345	MDR17 Mobile Direct Radiographic System
Photos		

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device. The MDR17 Mobile Direct System uses similar radiographic x-ray system technology to the predicate device. The differences in the subject device, such as the x-ray generator, tube crane, collimator, and x-ray tube, do not affect the safety or effectiveness of the device. The MDR17 Mobile Direct System can use a wireless flat panel detector similar to the predicate device, and the differences do not adversely affect the safety or effectiveness of the radiographic x-ray system.

The properties of the subject device presented in the comparison table above and described throughout this submission do not differ significantly from the legally marketed predicate device with regards to fundamental scientific technology, nor do they reflect a significant change in the indications for use. The differences between the subject device and the legally marketed predicate device have been assessed using Risk Management and through third-party evaluation using FDA-recognized consensus standards. The results of these efforts demonstrate that the device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness than the predicate.

9. Performance Testing (Bench). Del Medical claims conformance to a signed statement of performance standards. This submission contains performance data and test results to demonstrate conformance with special controls for medical devices containing software for a moderate level of concern per the FDA document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

EMC, mechanical safety, and electrical safety were evaluated according to various FDA-recognized consensus standards (see Table below). In conclusion, the identified risk of EMC, mechanical, and electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. Clinical testing is not required for a determination of substantial equivalence.

Table of Conformance to Consensus Standards

Recognition Number	Product Area	Standard Reference Number	Standard Title and Edition
19-5	General	AAMI ES60601-1	AAMI / ANSI ES60601-1:2005/(R)2012 And C1:2009/(R)2012 And, A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod)
19-1	General	IEC 60601-1-2	IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
12-210	Radiology	IEC 60601-1-3	IEC 60601-1-3 Edition 2.0 2008-01, Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment
5-89	General	IEC 60601-1-6	IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
12-274	Radiology	IEC 60601-2-54	IEC 60601-2-54 Edition 1.0 2009-06, Medical Electrical Equipment - Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Radiography And Radioscopy [Including: Technical Corrigendum 1 (2010), Technical Corrigendum 2 (2011)]
5-87	General	IEC 62366	IEC 62366 Medical devices – Application of usability engineering to medical devices

9. Performance Testing (Clinical). Because the digital x-ray receptor panel has already received FDA clearance, clinical testing was not required.

10. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features, including an emergency stop button, are incorporated into the system design. In addition, operation of the MDR17 Mobile Direct System is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed. Furthermore, the intended operators of the MDR17 Mobile Direct System are health care professionals familiar with and responsible for the x-ray examinations being performed. To minimize electrical, mechanical, and radiation hazards, Del Medical, Inc. adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

11. Conclusion as to Substantial Equivalence

The MDR17 Mobile Direct System is intended for the same use as the RadPRO® Mobile 40kW; (K161345.) It uses components similar to those cleared for the RadPRO® Mobile 40kW. It is Del Medical, Inc.'s opinion that the MDR17 Mobile Digital System is substantially equivalent to the cleared predicate device, the RadPRO® Mobile 40kW.