JUL 17 2014

510(k) Summary K140825
Submitted by Del Medical, Inc.
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Bloomingale, IL 60108
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(Fax) 847.288.7011
Prepared by: Marc Lorenzo, Vice President
Date Prepared: June 4, 2014

1. **Identification of the Device:**
   Proprietary-Trade Name: DelWorks DR System
   Classification Name: Stationary X-Ray System, Product Code MQB, Regulation 892.1680
   Common/Usual Name: Digital X-Ray Receptor Panel

2. **Equivalent legally marketed device**: Sedecal Digital Radiographic Upgrade, Model: SDRU-T, K130883

3. **Indications for Use (intended use)** DelWorks DR System is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. DelWorks DR System allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

4. **Description of the Device**: The DelWorks DR System represents the straightforward integration of a number of digital x-ray receptor panels using digital acquisition software. The DelWorks DR System is compatible with all modern HF generators. DelWorks DR System is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD) The DelWorks DR System is designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. Many of the compatible panels provide Auto-exposure detection. A synchronization module is available where exposure sync is required. This module connects between the digital panel and the x-ray high voltage generator. It provides "ready" synchronization and optical isolation between the two devices. Some of the detectors feature wireless Wi-Fi connection via a wireless access point. The software features Image Stitching (4 views can be combined into one single view) and other image enhancement features. The system software interacts with and controls technique factors of compatible generators via serial interfaces. DICOM output allows for transmission of images to the hospital radiology information system. The system employs Digital Radiography Operator Console (DROC) software, outputs a DICOM image. A USB "dongle" is provided to assure the authenticity of the software.

5. **Safety and Effectiveness, comparison to predicate device**. The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate devices. Clinical images collected demonstrate equal or better image quality as compared to our predicates.

6. Substantial Equivalence Chart

Characteristic	Sedecal Digital Radiographic Upgrade, Model: SDRU-T, K130883	DelWorks DR System K140825
Intended Use:	Sedecal Digital Radiographic Upgrade Model SDRU-T is intended for digital image capture use in general radiographic examinations, wherever conventional screen film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	DelWorks DR System is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. DelWorks DR System allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	This submission is for the Digital Panel and Software only, no generator or stand provided.
Digital Panels	Toshiba FDX4343R Detector Toshiba FDX3543RP Detector	Toshiba FDX4343R Toshiba FDX3543RP Thales Pixium Portable 2430EZ* Thales Pixium Portable 3543EZ* Konica Aero DR 14x17 Detector* Konica Aero DR 17x17 Detector* Fuji FDR D-EVO G35s Detector Fuji FDR D-EVO G35i Detector* Fuji FDR D-EVO G43i Detector* Fuji FDR D-EVO C24i Detector* Fuji FDR D-EVO C35i Detector* Fuji FDR D-EVO C43i Detector* Varian PaxScan 4336R Varian PaxScan 4343R Thales Pixium RAD 4143 Thales Pixium RAD 4343 *Wireless Wi-Fi
Software	Digital Radiography Operator Console (DROC) software, outputs a DICOM image	SAME as K130883, outputs a DICOM image.
DICOM	Yes	Yes
Interface	Ethernet	Ethernet or Wi-Fi
Power source	AC Line	AC Line
Electrical safety and EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.

7. Summary of Bench Testing Conducted: IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility. MTF and DQE measurements were supplied by the panel manufacturer in accordance with the FDA guidance document. Risk Analysis was conducted in accordance with FDA guidance documents. Software validation was performed using all panels. All of the digital panels have had previous successful 510(k) reviews.

8. Summary of Clinical Testing: Clinical images were acquired and evaluated by a board certified radiologist who concluded the images were of good diagnostic quality.

9. Conclusion: After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Del Medical Inc that the DelWorks DR System is 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 17, 2014

Del Medical, Inc.
% Mr. Daniel Kamm
Principle Engineer
8870 Ravello Court
NAPLES FL 34114

Re: K140825
Trade/Device Name: DelWorks DR System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 12, 2014
Received: June 16, 2014

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.

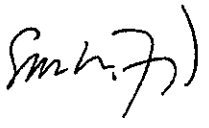
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
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 on last page.

510(k) Number *(if known)*
K140825

Device Name
DelWorks DR System

Indications for Use *(Describe)*
The DelWorks DR System is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. DelWorks DR System allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

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)

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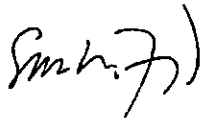
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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