DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

December 14, 2015

Re: K152767
Trade/Device Name: OTC12D Auto Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: November 23, 2015
Received: November 30, 2015

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,

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)*
K152767

Device Name
OTC12D Auto Radiographic System

Indications for Use *(Describe)*
The OTC12D Auto System is a radiographic system used in hospitals, clinics, and medical practices. The OTC12D Auto System enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult, and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critically ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The OTC12D Auto System is not meant for mammography. The OTC12D Auto System can use a mobile (wired) or portable (wireless) digital detector (not provided with system) for generating diagnostic images by converting x-rays into electronic signals. The OTC12D Auto System is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

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: Del Medical, Inc. OTC12D Auto X-Ray System
K152767

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

Date Prepared: December 8, 2015

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:

John Hartzell
Regulatory/Compliance Engineer
c/o Del Medical, Inc.
241 Covington Dr.
Bloomingdale, IL 60108
Phone: 847-288-7021

3. Device Name and Classification

Trade Name:	OTC12D Auto
Regulation Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90 KPR

4. Legally Marketed Predicate Device

Trade Name:	Multix Fusion
510(k) #:	K121513
Clearance Date:	August 10, 2012
Regulation Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90 KPR

5. Indications for Use

The OTC12D Auto System is a radiographic system used in hospitals, clinics, and medical practices. The OTC12D Auto System enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult, and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critically ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The OTC12D Auto System is not meant for mammography. The OTC12D Auto System can use a mobile (wired) or portable (wireless) digital detector (not provided with system) for generating diagnostic images by converting x-rays into electronic signals. The OTC12D Auto System is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

6. Device Description

The OTC12D Auto System is a permanently-installed diagnostic x-ray system for general purpose radiographic imaging for use in hospitals, clinics, and medical practices. It is intended to produce diagnostic x-ray images of human anatomy.

The OTC12D Auto System enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities, and may be used on pediatric, adult, and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. The resultant images are evaluated by a radiologist within the diagnostic process prior to the development of a treatment plan. It is not intended for fluoroscopy, angiography, or mammography.

The OTC12D Auto System typically includes a tube support, x-ray generator, x-ray tube, radiographic table, radiographic wall stand, and collimator. Systems that include the overhead tube crane provide auto-tracking of the tube crane based on the position of the radiographic table or wall stand.

Below are the specific components in various configurations to form a radiographic system used for general purpose radiographic imaging (see Table 1). Note that the customer supplies their own digital x-ray panel. We do not supply it.

Table 1. Components used in Del Medical, Inc. OTC12D Auto System

System Component Type	Manufacturer	Model Number(s)
Tube Support, Tube Crane	Del Medical Inc.	OTC-12D Auto
OR one of the Tube Stands listed below.		
Tube Support, Tube Stand	Del Medical Inc.	DFMTS
Tube Support, Tube Stand	Del Medical Inc.	DFMTS-PS
Tube Support, Tube Stand	Del Medical Inc.	FMTS
Tube Support, Tube Stand	Del Medical Inc.	FWFC
Generator		
X-ray Generator	CPI	CMP200
OR one of the alternate generators shown below.		
X-ray Generator, with User Interface	CPI	CMP200 DR
X-ray Generator, with User Interface	CPI	Indico 100
X-ray Generator, with User Interface	Siemens	Series Polydoros RF Rad 80, Model No. 10307360

System Component Type	Manufacturer	Model Number(s)
X-ray tube		
X-ray Tube	Toshiba	E7254FX, E7255FX, E7252FX, E7239FX, E7242FX
OR one of the x-ray tubes shown below.		
X-ray Tube	Varian	RAD14, RAD60, RAD92
X-ray Tube	Siemens	Series SV 150/40/80C-100, Model No. 4802349
Table		
Radiographic Table, Non-Elevating	Del Medical Inc.	RT-100
OR one of the tables shown below.		
Radiographic Table, Elevating	Del Medical Inc.	EV-650
Radiographic Table, Elevating	Del Medical Inc.	EV-800
Available Wall Stands		
Radiographic Wall Stand	Del Medical Inc.	3546E (VS100)
Radiographic Wall Stand	Del Medical Inc.	VS200
Radiographic Wall Stand	Del Medical Inc.	VS300
Available Collimators		
Collimator, Manual	Siemens	Series ML01 II, Model 10092611
Collimator, Automatic	Siemens	Series AL02 II eL, Model No. 10092614
Auto Collimator	Ralco	Ralco R221

The reason these models should be cleared under this 510(k) umbrella is that all of these components have been previously evaluated for safety and effectiveness via these main methods:

1. Previous clearances via the 510(k) route. (i.e. combinations.)
2. The fact that the components (generators, tube heads, and collimators) themselves do not require 510(k) notification because they are either Class I or are otherwise exempt.
3. The fact that they carry NRTL stickers meaning they all have been safety tested.
4. The fact that they have previous product reports showing compliance with the CFR Radiation Safety Standards.
5. The fact that our trained test technicians verify proper operation of every system installed in the field.

6. Substantial Equivalence

The OTC12D Auto radiographic x-ray system is substantially equivalent to the commercially available Siemens Multix Fusion (K121513) radiographic x-ray system with similar indications for use. The Multix Fusion was described in premarket notification K121513 which received FDA Clearance on August 10, 2012 (See Table 2 below).

Table 2: Predicate Device

Predicate Device Name & Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Multix Fusion, Siemens AG/Siemens Healthcare GmbH	K121513	August 10, 2012	Tube crane/Tube stand Wall stand, Table, ,X-ray tube, Collimator X-ray Generator, Operator console

The functional differences are between the OTC12D Auto and the Siemens Multix Fusion are shown below in Table 3.

Table 3: Subject and Predicate Device Comparable Properties

Comparable Properties	Subject Device: OTC12D Auto	Predicate Device: Siemens Multix Fusion K12113	Comparison Results
Indications for use	The OTC12D Auto System is a radiographic system used in hospitals, clinics, and medical practices. The OTC12D Auto System enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult, and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critically ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The OTC12D Auto System is not meant for mammography. The OTC12D Auto System can use a mobile (wired) or portable (wireless) digital detector (not provided with system) for generating diagnostic images by converting x-rays into electronic signals. The OTC12D Auto System is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	The Mulix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult, and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critically ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired) or portable (wireless) digital detector for generating diagnostic images by converting x-rays into electronic signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	Same
Tube crane/Tube stand	Overhead tube crane with manual or automated x-ray tube assembly movement; tube stand with manual x-ray tube assembly movement.	Overhead tube crane with manual or automated x-ray tube assembly movement.	Similar Functionality

Comparable Properties	Subject Device: OTC12D Auto	Predicate Device: Siemens Multix Fusion K12113	Comparison Results
Wall stand	Manual vertical movable wall stand, non-tiltable tray.	Manual vertical movable wall stand, tiltable tray.	Similar Functionality
Table	Free-floating and height-adjustable, maximum patient weight 800 lbs., working table height 22 inch to 34 inch; free-floating, maximum patient weight 700 lbs., working table height 33 inch.	Free-floating and height-adjustable, maximum patient weight 660 lbs., working table height 20-5/16 inch to 37-5/8 inch.	Same or Similar Functionality
X-ray tube	125 kV maximum operating voltage, 1.5 mm and 0.6 mm focal spots; 125 kV maximum operating voltage, 2.0 mm and 1.0 mm focal spots; 150 kV maximum operating voltage, 1.0 mm and 0.6 mm focal spots; 150 kV maximum operating voltage, 1.2 mm and 0.6 mm focal spots.	150 kV maximum operating voltage, 1 mm and 0.6 mm focal spots.	Similar Functionality
Collimator	ACSS collimator (Automatic Cassette Size Sensing); Manual format collimation.	ACSS collimator (Automatic Cassette Size Sensing).	Similar Functionality
X-ray Generator	Rated power: 100 kW, 80 kW, 65 kW, 50 kW, 40 kW, 32 kW.	Rated power: 80 kW, 65 kW, 55 kW.	Similar Functionality
Wireless detector	Supports various sizes of wireless detectors (not provided with system): 7" x 9.5"; 9.5" x 9.5"; 10" x 12"; 14" x 17" 12" x 12"; 10" x 8" 14" x 14"; 17" x 17" 7" x 17"	14" x 17"	Similar Functionality
Fixed detector	Supports various sizes of fixed detectors (not provided with system): 7" x 9.5"; 9.5" x 9.5" 10" x 12"; 14" x 17" 12" x 12"; 10" x 8" 14" x 14"; 17" x 17" 7" x 17"	17" x 17"	Similar Functionality
Conventional film/screen systems or CR cassettes	Film/Screen or CR Cassettes.	Film/Screen or CR Cassettes.	Similar Functionality
Operator console	GUI-based	GUI-based	Similar Functionality

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device

The OTC12D Auto System uses a similar radiographic x-ray system as the predicate device. The differences in the subject device, such as the x-ray generator, radiographic table, wall stand, tube crane, collimator, and x-ray tube, do not affect the safety or effectiveness of the device. The OTC12D Auto System can use a wireless or fixed flat panel detector (not provided with system) 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 (see Table 3) 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.

8. Performance Testing

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 4 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 4: 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

Recognition Number	Product Area	Standard Reference Number	Standard Title and Edition
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)]

9. 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 OTC12D Auto 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 OTC12D Auto 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.

10. Conclusion as to Substantial Equivalence

The OTC12D Auto System is intended for the same use as the Multix Fusion. It uses components similar to those cleared for the Multix Fusion (e.g. tube crane/tube stand, wall stand, table, x-ray tube, collimator, x-ray generator, operator console). It is Del Medical, Inc.'s opinion that the OTC12D Auto System is substantially equivalent to the cleared predicate device, the Multix Fusion.