April 10, 2023

Del Medical, Inc.
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K223550
Trade/Device Name: DMX
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: November 24, 2022
Received: November 25, 2022

Dear Daniel 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,

Digitally signed by Gabriela M. Rodal -S

For

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223550

Device Name
DMX

Indications for Use *(Describe)*

The DMX is a radiographic system used in hospitals, clinics, and medical practices. The DMX 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 DMX is not meant for mammography. The DMX 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 DMX 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: Del Medical, Inc. DMX X-Ray System, K223550

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

Date Prepared: March 25, 2023

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:

Greg Geary
Director of Quality and Regulatory
c/o Del Medical, Inc.
241 Covington Dr.
Bloomingdale, IL 60108
Phone: 847-288-7021

3. Device Name and Classification

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

4. Legally Marketed Predicate Device

510(k) Number:	K152767 (DEL Medical)
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:	KPR

5. Indications for Use

The DMX is a radiographic system used in hospitals, clinics, and medical practices. The DMX 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 DMX is not meant for mammography. The DMX 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 DMX is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes

6. Device Description

The DMX 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 DMX 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 DMX 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.

Available System Variations

DMX Part #	Description
DM-OTC18S	Automatic stitching and tracking overhead tube crane system
DM-OTC18T	Automatic tracking overhead tube crane system
DM-OTC18M	Overhead tube crane system
DM-FMT18T	Automatic tracking floor mounted tube stand system
DM-FMT18M	Floor mounted tube stand system
DM-FMT	Basic floor mounted tube stand system
DM-FWFC	Basic floor to wall / floor to ceiling tube stand system
DM-SARM	Straight arm system

Tube Supports, Radiographic Tables, and Wall Stands Compatibility

Structure Component	DM-OTC18S	DM-OTC18T	DM-OTC18M	DM-FMT18T	DM-FMT18M	DM-FMT	DM-FWFC	DM-SARM
OTC18S automatic stitching tube crane	X							
OTC18T automatic tracking tube crane		X						
OTC18M tube crane			X					
FMT18T automatic tracking tube stand				X				
FMT18M tube stand					X			
FMT basic tube stand						X		
FWFC floor-wall/ceiling basic tube stand							X	
Straight arm								X
EV800T elevating table with motorized receptor	X							
EV800 elevating table		X	X	X	X	X	X	
RT100 fixed height table						X	X	
MT500 mobile table			X		X	X	X	X
No table		X	X	X	X	X	X	X
VT300T tilting wall stand with motor	X							
VT300 tilting wall stand		X	X	X	X	X	X	
VS300 vertical wall stand			X	X	X	X	X	
VS100 basic vertical wall stand						X	X	
No wall stand		X	X	X	X	X	X	X

Generator Availability

Del Model	OEM	OEM Model
CM Series	Communications and Power Industries Inc.	CMP200, 32, 40, 50 kW
CMDR Series	Communications and Power Industries Inc.	CMP200DR 40, 50, 65, 80 kW
AN Series	Del Medical	Anthem: 30, 32, 40, 50 kW
RF Series	Siemens	Polydoros / Polydoros ESU 55, 65, 80 kW

6. Substantial Equivalence

The DMX radiographic x-ray system is substantially equivalent to the commercially available OTC12D Auto (K152767) radiographic x-ray system with identical. indications for use. The OTC12D Auto was described in premarket notification K152767 which received FDA Clearance on December 14, 2015 (See Table below).

Subject and Predicate Device Comparable Properties:

Comparable Properties	Predicate OTC12D Auto K152767	Subject Device DMX System	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 DMX System is a radiographic system used in hospitals, clinics, and medical practices. The DMX 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 DMX System is not meant for mammography. The DMX 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 DMX System 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.	Overhead tube crane with manual or automated x-ray tube assembly movement.	SAME
Wall stand	Manual vertical movable wall stand, non-tiltable tray.	Manual vertical movable wall stand, tiltable tray.	Better Functionality
Table	Free-floating and height-adjustable, maximum patient weight 800 lbs.,	Free-floating and height-adjustable, maximum patient weight 800 lbs.,.	Same
Available X-ray tubes	Canon, Varex, or Siemens	Canon, Varex, or Siemens	SAME
Collimator	R221 (Ralco) or ML03, AL02 (Siemens)	R221 (Ralco) or ML03, AL02 (Siemens)	SAME
Available X-ray Generators	32, 40, 50, 65, 80, 100 kW	30, 32, 40, 50, 55, 60, 80 kW	Similar range of sizes

Comparable Properties	Predicate OTC12D Auto K152767	Subject Device DMX System	Comparison Results
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"	SAME	SAME
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"	SAME	SAME
Conventional film/screen systems or CR cassettes	Film/Screen or CR Cassettes.	Film/Screen or CR Cassettes.	SAME
Operator console	GUI-based	GUI-based	SAME
System Appearance (Photo)			Very similar appearance, same functionality

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

The DMX System uses similar or identical radiographic x-ray system components to 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 DMX System can use a wireless or fixed flat panel detector (not provided with system) same models as 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.

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.

The system was tested and certified to comply with the Radiation Safety Performance Standards of Title 21 of the CFR.

Cybersecurity controls have been implemented per the FDA Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff.

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.

Conformance to Consensus Standards: The Del Medical DMX radiographic x-ray system complies with the applicable portions of the following standards:

Recognition Number	Standard Reference Number	Standard Title and Edition
19-4	AAMI ES60601-1	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, 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)
19-8	IEC 60601-1-2	IEC60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
12-269	IEC 60601-1-3	IEC 60601-1-3 Edition 2.1 2013-04 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	Standard Reference Number	Standard Title and Edition
5-89	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
12-317	IEC 60601-2-54	IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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 DMX 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 DMX 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 DMX System is intended for the same uses as the OTC12D Auto. It uses components similar to those cleared for the OTC12D Auto (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 DMX System is substantially equivalent to the cleared predicate device, the OTC12D Auto.