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

September 22, 2016

CMT Medical Technologies, Ltd.
% Ms. Lilia Schlosberg
Director of Quality and Regulatory Affairs
Hacarmel St. Bld 7/2, POB 111, Industrial Park
Yoqneam Ilit, 20692
ISRAEL

Re: K162224
Trade/Device Name: ArtPix Mobile EZ2GO
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: August 21, 2016
Received: August 24, 2016

Dear Ms. Schlosberg:

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

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)*
K162224

Device Name
ArtPix Mobile EZ2GO

Indications for Use *(Describe)*
The ArtPix Mobile EZ2GO, is intended for use in general radiographic examinations by qualified/trained doctors or technicians, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography.
ArtPix Mobile EZ2GO allows imaging of the skull, chest, shoulders, spine, abdomen, and extremities. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position

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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1. 510(k) Summary K162224

1.1. Proprietary Device Name:

ArtPix Mobile EZ2GO

1.2. Establishment Name and Registration Number of Submitter

Manufacture Name:
CMT Medical Technologies Ltd.
Hacarmel St, Building 7/2 Industrial Park
Yokneam Illit 20692
Israel

Registration: 8030112

Submission contact:
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1.3. Device Classification

Classification Name: Stationary X-Ray System
Classification Regulation: 21CFR 892.1680
Classification Panel: Radiology
Device Class: Class II
Classification Product Code: KPR (System X-Ray Stationary)
Subsequent Product Code: MQB - solid-state X-Ray imager (flat panel / digital imager)

1.4. Reason for 510K Submission

Special 510K Submission

1.5. Identification of Legally Marketed equivalent Devices

PrestoDR 4143 K110849

Classification Name: Stationary X-Ray System
Classification Regulation: 21CFR 892.1680
Classification Panel: Radiology
Device Class: Class II
Classification Product Code: KPR (System X-Ray Stationary)
Subsequent Product Code: MQB - solid-state X-Ray imager (flat panel / digital imager)

1.6. Device Description

The modified ArtPix Mobile EZ2GO is a flexible high-resolution Digital Radiography (DR) system that is designed to provide fast and smooth radiography examinations of sitting, standing or lying patient Imaging. The modified ArtPix Mobile EZ2GO consists of the following components: Tablet Computer, Flat Panel Detectors, Detector Removable batteries & Charger, and other optional components such as External Monitor for Docking Station, USB HUB, Bluetooth DAP device and Fix Room Access Point Support. Images may be transferred via a network using DICOM protocol for printing and storage in PACS.

The modified ArtPix Mobile EZ2GO can be used in combination with any conventional analog radiography system currently using film screen or CR, fixed or mobile, or other system capable of producing general radiography exposures.

The modified Artpix Mobile EZ2GO detector can be shared between multiple Artpix Mobile EZ2GO systems.

1.7. The Device Intended and Indications for Use

Indications for use

The ArtPix Mobile EZ2GO, is intended for use in general radiographic examinations by qualified/trained doctors or technicians, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography.
ArtPix Mobile EZ2GO allows imaging of the skull, chest, shoulders, spine, abdomen, and extremities. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Statement: CMT Medical Technologies Ltd hereby states that in terms of fundamental scientific technology, indication for use, safety and effectiveness the submitted modified The ArtPix Mobile EZ2GO device is substantially equivalent to the currently marketed predicate device PrestoDR 4143 K110849.

1.8. Standards & Guidance

The Modified ArtPix Mobile EZ2GO complies with the following International and FDA recognized consensus and FDA Guidance:

- EN/IEC/UL IEC 60601-1 3rd edition “Medical Electrical equipment. Part 1: General requirements for safety”.
- IEC 60601-1-2 3rd edition Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6:2013-Ed.3.1 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304:2006 Medical device software — Software life cycle processes

- IEC 60601-2-54:2009-Ed.1.0 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009-Ed.1.0/Cor.1:2010

- IEC 60601-1-3:2008-Ed.2.0 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment

- IEC TR 60878, “Graphical symbols for electrical equipment in medical practice”

- NEMA PS 3.1 1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set.

- EN ISO 14971:2012 Application of risk management to medical devices

- ISO 15223-1:2012, Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied

- CFR 1020.30 Diagnostic x-ray systems and their major components.

- CFR 1020.31 Radiographic equipment.

- Device specific guidance document, titled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices August 6, 1999,"

- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  ISO 10993-1:2009/Cor.1:2010

1.9. Summary of the Basis for Substantial Equivalence

This submission of the ArtPix Mobile EZ2GO modification presents changes of the legally marketed unmodified device PRESTODR 4143 K110849 .

The ArtPix Mobile EZ2GO is a Digital Radiography system, featuring the Pixium Portable 3543EZ / 2430EZ family Portable Flat Panel Detectors manufactured by Trixell (Pixium Portable 3543EZ, Pixium Portable 3543EZ-C,Pixium Portable 3543EZh-C, Pixium Portable 3543EZ-G, Pixium Portable 2430EZ-C, Pixium Portable 2430EZ-G, Pixium Portable 3543EZh Siemens branded "MAX wi-D", Pixium Portable 2430EZ Siemens branded "MAX mini") and CMT's proprietary technology, which incorporates a tablet computer and state of the art object-oriented software.
The legally marketed PRESTODR 4143 K110849 has been modified: To integrate the Pixium 3543EZ / 2430EZ family Portable Flat Panel Detectors and improve cost effectiveness. Aging technologies and components (hardware and software) have been redesigned. The devices major functions, intended use and principle of operation were not changed.

The modified device ArtPix Mobile EZ2GO consists of almost the same architecture, technologies and algorithms of the predicate PRESTODR 4143 K110849. The topics of the design modifications are presented below:

Hardware modifications:

The predicate device PRESTODR 4143 K110849 was minorly modified:

1. Predicate device PRESTODR 4143 K110849 supports Pixium 4143 FPD (Flat Panel Detector) and Pixium Portable 3543 FPD. The modified device ArtPix Mobile EZ2GO is using the Pixium 3543EZ / 2430EZ family Portable Flat Panel Detectors. The Pixium Flat Panel Detectors supported in the modified device ArtPix Mobile EZ2GO have the same architecture and functionality as in the PRESTODR 4143 K110849, and have already been cleared by FDA in the currently marketed (K141440) dicomPACS DX-R - Oehm und Rehbein GmbH.
2. The PRESTODR 4143 K110849 PC computer was replaced by ArtPix Mobile EZ2GO tablet. In terms of technical performance (Processing Capabilities, Display and Touch), the tablet is no worse than the stationary PC used in PrestoDR 4143, except for hard drive capacity, which is a marginal feature with no impact on the fundamental scientific technology, indication for use, safety and effectiveness.

Software modifications:

The software basic functions were not changed. User interface was changed in order to be up-to-date with the modern applications. Additional code was added to support the Pixium 3543EZ / 2430EZ family Portable Flat Panel Detectors.
The submitted device description includes enhanced connectivity, processing time, convenience of use, production ability, and serviceability.

Summary: This submission presents design changes. The modified device ArtPix Mobile EZ2GO is compared to the predicate PRESTODR 4143 K110849. It has the same intended use

(see the comparison table, section 4.2below). The changed device has almost the same technological and performance characteristics of the predicate devices (see the comparison table, section 0) and, in CMT's opinion, these modifications do not raise new types of safety or effectiveness concerns. This submission includes detailed device descriptive and performance information (see sections 1-6 and appendices A-H) that demonstrate that the device is substantially equivalent to the predicate device.

1.9.1. Comparison of indications for use

	Comparison content	***PrestoDR 4143***	***ArtPix Mobile EZ2GO***
1	**K number**	K110849	
2	**Owner**	CMT Medical Technologies Ltd	CMT Medical Technologies Ltd
3	**Indication for use**	The PrestoDR 4143 , is intended for use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. PrestoDR 4143 allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis and extremities.	The ArtPix Mobile EZ2GO, is intended for use in general radiographic examinations by qualified/trained doctors or technicians, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ArtPix Mobile EZ2GO allows imaging of the skull, chest, shoulders, spine, abdomen, and extremities. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

The indications of use of the predicate PrestoDR 4143 K110849 and the modified ArtPix Mobile EZ2GO are identical, except for slight language modifications.

1.9.2. Performance & Technological Characteristics Comparison

1.9.2.1. Detectors

a. Detectors with CsI scintillator

System	Predicate K110849 PrestoDR 4143		ArtPix EZ2GO					
Model	**Pixium 4143C**	**Pixium Portable 3543**	**Pixium Portable 3543EZ**	**Pixium Portable 3543EZ-C**	**Pixium Portable 3543EZh-C**	**Pixium Portable 2430 EZ-C**	**Pixium Portable 3543EZh (MAX wi-D)**	**Pixium Portable 2430EZ (MAX mini)**
Pixel Pitch	148 µm	144 µm	148 µm					
Active Image Area	41 x 42.5 cm (16.2" x 16.7") 2775 x 2874 usable pixels	34.1x 43.2 cm^2 (13.4" x17" / 2372 x 3000 usable pixels	33.7 x 41.4 cm (13.26" x 16.30" / 2280 x 2800 usable pixels)	34.4 x 42.1 cm (13.54" x 16.57" / 2330 x 2846 usable pixels)	34.4 x 42.1 cm (13.54" x 16.57" / 2330 x 2846 usable pixels)	22.2 x 28.4 cm (8.74" x 11.18" / 1500 x 1920 usable pixels)	34.4 x 42.1 cm^2 (13.54" x 16.57" / 2330 x 2846 usable pixels)	22.2 x 28.4 cm^2 (8.74" x 11.18" / 1500 x 1920 usable pixels)
Dynamic Range	16 bits	16 bit	16 bit					
DQE (typical values)	64% at 0 lp/mm	66% at 0 lp/mm	66% at 0 lp/mm					
	52% at 1 lp/mm	51% at 1 lp/mm	50% at 1 lp/mm					
	42% at 2 lp/mm	39% at 2 lp/mm	40% at 2 lp/mm					
	25% at 3 lp/mm	23% at 3 lp/mm	24% at 3 lp/mm					
Weight	11.5 Kg	4.7 Kg	2.8 Kg		3.0 Kg	1.6 Kg	3.2Kg	1.6 Kg
	25.3 lbs	9.5 lbs	6.17 lbs		6.61 lbs	3.52 lbs	7.05 lbs	3.52 lbs

The Pixium Portable 3543EZ / 2430EZ FPD family of detectors that are used in the modified ArtPix Mobile EZ2GO has already been cleared by FDA in in the currently marketed (K141440) dicomPACS DX-R

b. Detectors with Gadox scintillator

System	Predicate K110849 PrestoDR 4143	ArtPix EZ2GO	
Model	**Pixium 4143G**	**Pixium Portable 3543EZ-G**	**Pixium Portable 2430 EZ-G**
Pixel Pitch	148 µm	148 µm	
Active Image Area	41 x 42.5 cm (16.2" x 16.7") 2775 x 2874 usable pixels	33.7 x 41.4 cm (13.26" x 16.30" / 2280 x 2800 usable pixels)	22.2 x 28.4 cm (8.74" x 11.18" / 1500 x 1920 usable pixels)
Dynamic Range	16 bits	16 bit	
MTF (typical values)	37% at 0 lp/mm	37% at 0 lp/mm	
	25% at 1 lp/mm	25% at 1 lp/mm	
	17% at 2 lp/mm	17% at 2 lp/mm	
	7% at 3 lp/mm	7% at 3 lp/mm	
Weight	11.5 Kg	2.8 Kg	1.6 Kg
	25.3 lbs	6.17 lbs	3.52 lbs

The Pixium Portable 3543EZ / 2430EZ FPD family of detectors that are used in the modified ArtPix Mobile EZ2GO has already been cleared by FDA in in the currently marketed (K141440) dicomPACS DX-R

1.9.2.2. System

System		Predicate K110849 PrestoDR 4143	ArtPix EZ2GO
Workstation Computer * min requirements	Processor*	i3-540	i5-4310U
	Memory*	2GB, DDR3, 1333 MHz RAM	8GB
	Operating System	Windows XP	Windows 7
	Interfaces	One 1Gig LAN for FPD (WiFi access point) and One 1Gig LAN for DICOM network data connection	One WiFi AP for FPD and One 1Gig LAN for DICOM network data connection
	Display	Color 17"/19" LCD Touch Screen, 1280x1024 pixels	10.1" LCD 10-Point Multi Touch Screen Optional 24" (with docking station) 1920x1200 pixels
	Acquisition - Patient data entry	Manually or automatically from the DICOM Worklist	Manually or automatically from the DICOM Worklist
	Acquisition - Patient data entry Reviewing & Processing	Urgent patient registration (including update)	Urgent patient registration (including update)
		Multiple Examinations Handling	Multiple Examinations Handling
		User-selectable images	User-selectable images
	Reviewing & Processing	Window/level	Window/level
		Window polarity inversion	Window polarity inversion
		Image inversion: Rotation of the image by 90°, 180° and 270°. Horizontal and vertical reverse.	Image inversion: Rotation of the image by 90°, 180° and 270°. Horizontal and vertical reverse.
		Electronic zoom with pan & scroll capabilities	Electronic zoom with pan & scroll capabilities
		Segmentation based image processing and contrast enhancement	Segmentation based image processing and contrast enhancement
		Operator selectable anatomical programs	Operator selectable anatomical programs Automatic background filming
		Preview image typically within 6-7 seconds after exposure @ 0.5sec integration time	Preview image typically within 4 seconds after exposure @ 0.5sec integration time
		Selectable automatic, semi-automatic or manual storage and printing	Selectable automatic, semi-automatic or manual storage and printing
	DICOM 3.0 Connectivity	Print: Interface to up to 10 DICOM-compliant printers	Print: Interface to up to 10 DICOM-compliant printers
		Store: Interface to up to 10 DICOM Storage servers	Store: Interface to up to 10 DICOM Storage servers
		MWL: Interface to Hospital / Radiology information system's Modality Worklist including patient registration and study information (optional)	MWL: Interface to Hospital / Radiology information system's Modality Worklist including patient registration and study information (optional)
	Disk Storage*	Hard-disk: 500 GB (or higher capacity) enabling at least 15,000 image storage.	Hard-disk: 250 GB SSD (or higher capacity) enabling at least 7,500 image storage. Drive is used for temporary storage only, and not for archive purpose. From usability stand-point 7,500 images is much more than needed.
	Dimensions	36 (H) x 18.3 (W) x 42 (L) cm	27 (H) x 18.8 (W) x 2 (L)cm
		14.2" (H) x 7.2" (W) x 16.5" (L)	10.6" (H) x 7.4" (W) x 0.8" (L)
	Weight	10.1 Kg	1.09 Kg
		22.2 lbs	2.4 lbs

System		Predicate PrestoDR 4143	ArtPix EZ2GO
Bucky		Optional item, including grid and AEC	Provided by OEM In stationary rooms only (including grid and AEC). No electrical connection to Artpix EZ2GO.
Power Distribution Unit		Provides power to FPD	N/A (FPD is powered by a battery)
Power Requirements	AC Voltage	100-240V	100-240V
	Max Power	700VA	92VA (27VA (Monitor), 65VA (Tablet))
	Line Frequency	50-60 Hz	50-60 Hz
Digital System Storage and Transport	Temperature	-20 - 60°C	-20 - 60°C
	Relative Humidity	10 - 90%	10 - 90%
	Atmospheric Pressure	70 - 106 kPa	70 - 106 kPa
Regulatory Compliance		IEC 60601-1-1, IEC 60601-1-2 (only when all system's hardware supplied by Thales) ISO 15223, IEC 60878, ISO 14971 Compliant with HIPAA requirements.	IEC 60601-1-1, IEC 60601-1-2 (only when all system's hardware supplied by Thales) ISO 15223, IEC 60878, ISO 14971 Compliant with HIPAA requirements.

1.10. Verification, Validation (V&V)

The V&V processes of the modified PrestoDR Portable have been preformed in several steps as follows:

a. The programmers performed software unit tests during the coding phase. Detected bugs were corrected on line.
b. The Software was integrated into a software version, which was installed into the target ArtPix Mobile EZ2GO modified system. A software test document was prepared prior to the tests. That document presents the case scenario (test protocol) and includes the pass/ fails ("expected results") criteria. The software was integrated and tested with the target system. The (positive /negative) results were documented in the test document.
c. System bench tests were performed by CMT Medical Technologies Ltd. Residual software anomalies that were detected during this stage were recorded to and corrected.
d. The system performance of the modified ArtPix Mobile EZ2GO was validated by measuring the image quality.
e. RMF and System Requirements were tested. No critical, Safety, efficacy or blocking remained open.

Conclusion:

The modified ArtPix Mobile EZ2GO system passed its acceptance criteria and is recommended for release.