CMT Medical Technologies, Ltd.
℅ Dror Wertman
Director of Quality Assurance and Regulatory Affairs
7/2 Hacarmel St., POB 111, Industrial Park
Yokneam Ilit, 20692
ISRAEL

September 3, 2020

Re: K202235
Trade/Device Name: ArtPIX DRF
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, MQB
Dated: August 4, 2020
Received: August 7, 2020

Dear Dror Wertman:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202235

Device Name
ArtPIX DRF

Indications for Use *(Describe)*
The ArtPIX DRF is a digital image acquisition system to be used with integrated solid state detector, during radiography or fluoroscopy x-ray examination, to capture digitalize, review images and format images according to DICOM protocol to be sent through network connection.

This device is not intended for mammography use.

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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1. Special 510(k) Summary

K202235

1.1. Proprietary Device Name:

ArtPIX DRF

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

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1.3. Device Classification

Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21CFR 892.1650
Device Class:	Class II
Classification Product Code:	JAA - Image-intensified fluoroscopic x-ray system
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

Duet DRF K103038

Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21CFR 892.1650
Device Class:	Class II
Classification Product Code:	JAA - Image-intensified fluoroscopic x-ray system
Subsequent Product Code:	MQB - solid-state X-Ray imager (flat panel / digital imager)

1.6. The Device Intended and Indications for Use

Indications for use
The ArtPIX DRF is a digital image acquisition system to be used with integrated solid state detector, during radiography or fluoroscopy x-ray examination, to capture, digitalize, review images and format images according to DICOM protocol to be sent through network connection.

This device is not intended for mammography use.

Statement: CMT Medical Technologies Ltd hereby states that in terms of fundamental scientific technology, indications for use, safety and effectiveness the submitted modified ArtPIX DRF device is substantially equivalent to the currently marketed predicate device Duet DRF K103038.

1.7. Device Description

The modified ***ArtPIX DRF*** is a dynamic digital radiography system including fluoroscopy and radiography capabilities.
The system application is based on Windows 10 operating system. The object-oriented software performs real-time image processing (based on parallel computing), and full procedures storage. The DICOM 3.0 IHE compliant connectivity provides the tools to transmit patient demographics, examinations and image data in digital format.

Parameters for X-ray exposure, review, post-processing operations and filming can be set up from a single console, significantly increasing clinical efficiency.

The modified ***ArtPix DRF*** operates in connection with the dynamic Pixium 2121, 3030, 4343 flat panel detectors and 2430, 3543 portable flat panel detectors (made by Thales of Moirans, France).

The modified ***ArtPix DRF*** is intended for OEMs and Integrators that will integrate the product with their R&F table as a digital supplement.

1.8. Standards & Guidance

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

- IEC 60601-1:2005/A1:2012, Medical electrical equipment - Part 1: General requirements for safety and essential performance. FDA/CDRH recognition number 19-4.

- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. FDA/CDRH recognition number 19-8.

- IEC 60601-1-3:2008, AMD1:2013, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment. FDA/CDRH recognition number 12-269.

- IEC 60601-1-6:2010 + A1:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. FDA/CDRH recognition number 5-89.

- IEC 62366: 2015 Application of Usability Engineering to Medical Devices (Edition 1.0 2015). FDA/CDRH recognition number 5-114.

- IEC 62304:2006+A1 2015, Medical device software — Software life cycle processes. FDA/CDRH recognition number 13-79.

- IEC 60601-2-43:2010+AMD1:2017, Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures. FDA/CDRH recognition number 12-308.

- IEC 60601-2-54:2009+AMD1:2015, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. FDA/CDRH recognition number 12-296.

- ISO 14971 Second edition 2007, Application of risk management to medical devices. FDA/CDRH recognition number 5-40.

- IEC/TR 60878: 2015, “Graphical symbols for electrical equipment in medical practice”. FDA/CDRH recognition number 5-104.

- NEMA PS 3.1 - 3.20; Digital Imaging and Communications in Medicine (DICOM) Set (2016). FDA/CDRH recognition number 12-300.

- ISO 15223-1:2016, Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied. FDA/CDRH recognition number 5-117.

- ISO 10993-1:2009 (4th edition), Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. FDA/CDRH recognition number 2-220.

- IEC 62220-1-1: 2015, Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging. FDA/CDRH recognition number 12-289.

- IEC 62220-1-3: 2008, Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging. FDA/CDRH recognition number 12-214.

- IEC 62494-1: 2008, Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography. FDA/CDRH recognition number 12-215.

- IEC 61910-1: 2014, Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy. FDA/CDRH recognition number 12-290.

- NEMA XR 27 Amendment 1-2013, X-ray equipment for interventional procedures - User Quality Control Mode. FDA/CDRH recognition number 12-286.

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

- CFR 1020.31 Radiographic equipment

- CFR 1020.32 Fluoroscopic equipment

- Device specific guidance document, titled "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices", September 1, 2016 (document number 644)

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and FDA Staff (draft document number 1825).

- Pediatric information for x-ray imaging device premarket notifications (document number 1771)

- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (document number 337).

1.9. Summary of the Basis for Substantial Equivalence

This submission of the ArtPix DRF modification presents changes of the legally marketed unmodified device Duet DRF K103038.

The modified ***ArtPIX DRF*** is a dynamic digital radiography system including fluoroscopy and radiography capabilities. The system incorporates Flat Panel Detectors.

The legally marketed Duet DRF K103038 has been modified, to integrate additional models of flat panel detectors (Pixium 4343 FL, Pixium 4343 FL model 4, Pixium 2121S-A, Pixium 3030S-A).
An optional second Portable Flat Panel Detector was integrated (Pixium 3543EZ / 2430EZ / 3543DR family). Modifications for improvement of cost effectiveness were implemented. Aging technologies and components (hardware and software) have been redesigned. The devices major functions, intended use and principle of operation were not changed.

1.9.1. Comparison of indications for use

	Comparison content	***Duet DRF***	***ArtPix DRF***
1	**K number**	K103038	
2	**Owner**	CMT Medical Technologies Ltd	CMT Medical Technologies Ltd
3	**Indication for use**	The Duet DRF is a digital image acquisition system to be used with integrated solid state detector, during radiography or fluoroscopy x-ray examination, to capture digitalize, review images and format images according to DICOM protocol to be sent through network connection. This device is not intended for mammography use.	The ArtPIX DRF is a digital image acquisition system to be used with integrated solid state detector, during radiography or fluoroscopy x-ray examination, to capture digitalize, review images and format images according to DICOM protocol to be sent through network connection. This device is not intended for mammography use.

The indications of use of the predicate Duet DRF K103038 and the modified ArtPix DRF are identical.

1.9.2. Performance & Technological Characteristics Comparison

1.9.2.1. Detectors

a. Dynamic Detectors

System		Predicate Duet DRF K103038	Modified ArtPIX DRF				
Model		**Pixium RF 4343**	**Pixium RF 4343**	**Pixium 4343 FL**	**Pixium 4343 FL (Model 4)**	**Pixium 3030S-A**	**Pixium 2121S-A**
Approved by FDA 510k #		K103038	K103038	K160301	---	---	K183040
Pixel Pitch		148 µm	Same detector as in Predicate Duet DRF	148 µm	148 µm	154 µm	154 µm
Active Image Area		42.5 x 42 cm 2875 x 2840 usable pixels		42.5 x 42 cm 2874 x 2840 usable pixels	42.5 x 42 cm 2874 x 2840 usable pixels	30.1 x 30.1 cm 1956 x 1956 usable pixels	20.7 x 20.7 cm 1344 x 1344 usable pixels
Dynamic Range		16 bits		16 bits	16 bits	16 bits	16 bits
X-ray generator voltage range		40-150 kVp		40-150 kVp	40-150 kVp	40-150 kVp	40-150 kVp
Maximum frame rate (full image) – Cont. fluoroscopy		18 FR/sec		16 FR/sec	30 FR/sec	12 FR/sec	25 FR/sec
DQE (typical values)	@ 0 lp/mm (typ)	65%		65%	73%	77%	77%
	@ 2 lp/mm (typ)	35%		32%	35%	30%	33%
Image interface		Camera Link & LVDS		Camera Link & LVDS	Ethernet	Ethernet	Ethernet

- The Pixium RF 4343 detector has been cleared by FDA in the predicate Duet DRF (K103038).
- The Pixium 4343 FL detector has been cleared by FDA in the currently marketed (K160301) Platinum dRF Imaging System. It is manufactured by the same manufacturer of the already cleared RF 4343 detector in the predicate device and is using the same technology.
- Pixium 4343 FL Model 4 FPD is manufactured by the same manufacturer of the already cleared RF 4343 FPD (Thales from France) used in the predicate device. It is using the same technology and has almost same performance of the RF 4343 used in the predicate Duet DRF.

- Pixium 2121S-A detector has been cleared by FDA in the currently marketed Zenition 70 (K183040). It allows an effective area of approximately 21 x 21 cm. It is also manufactured by the same manufacturer of the already cleared RF 4343 FPD (Thales from France) used in the predicate device and it is using the same technology.
- Pixium 3030S-A FPD is also manufactured by the same manufacturer of the already cleared RF 4343 FPD (Thales from France) used in the predicate device. The 3030S-A is using the same technology and has almost same performance as the already cleared 2121S-A detector, and allows an effective area of approximately 30 x 30 cm.

b. Static Detectors

Model	Pixium Portable 3543EZ-C	Pixium Portable 2430EZ-C	Pixium Portable 3543DR-CS
Approved by FDA 510k #	K162224	K162224	K192541
Pixel Pitch	148 µm	148 µm	160 µm
Active Image Area	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)	34.5 x 42.6 cm (13.58" x 16.77" / 2156 x 2662 usable pixels)
Dynamic Range	16 bit	16 bit	16 bit
DQE (typical values)	70% at 0 lp/mm	66% at 0 lp/mm	70% at 0 lp/mm
	50% at 1 lp/mm	50% at 1 lp/mm	51% at 1 lp/mm
	40% at 2 lp/mm	40% at 2 lp/mm	42% at 2 lp/mm
	24% at 3 lp/mm	24% at 3 lp/mm	22% at 3 lp/mm
Weight	2.8 Kg	1.6 Kg	3.1 Kg
	6.2 lbs	3.5 lbs	6.8 lbs

The modified ArtPIX DRF is also using optional Pixium Portable 3543EZ / 3543DR-CS/ 2430EZ family of static Portable Flat Panel Detectors. The Pixium Portable 3543EZ / 2430EZ detectors have been cleared by FDA (K162224) in the currently marketed CMT Medical Technologies ArtPIX Mobile EZ2GO system.
The Pixium Portable 3543DR-CS detector has been cleared by FDA (K192541) in the currently marketed Allengers Medical Systems Limited, DigiX FDX system.

1.9.2.2. System

	Comparison content	*Predicate Duet DRF*	*ArtPIX DRF*
	K number	K103038	
	Owner	CMT Medical Technologies Ltd	CMT Medical Technologies Ltd
	Infrastructure	PC based workstation	PC based workstation
	Operating System	Windows XP	Windows 10
	Graphical User Interface (GUI)	User interactive, Windows based	User interactive, Windows based
	In Room Monitor Interface	BNC (analog)	Display-port (digital)
	Digitization depth	16 Bits	16 Bits
	FPD	Thales Pixium RF 4343	Thales Pixium 4343RF / FL 4343, FL 4343 (model 4), 2121S-A, 3030S-A
	2nd FPD Option	NA	Thales Pixium 3543EZ-C, 2430EZ-C, 3543DR-CS
	Continuous fluoroscopy rate (full frame)	Up to 30 fps	Up to 30 fps
	Pulsed Fluoroscopy rate (full frame)	Up to 15 fps	3.75, 7.5, 15 fps
	Fluoro store	0.5 fps Up to 15 fps	Up to 30 fps
	Anatomically programmed protocols	Yes	Yes
	User-selectable Display manipulations	Yes	Yes
	Image Stitching	NA	Yes (2-5 static images)
	Anti-virus SW	Trendmicro	Whitelist McAfee, Windows defender
	Communication	DICOM compatibility (Store, Print, MWL)	DICOM compatibility (Store, MWL, RDSR, Storage Commitment, MPPS)
	Electrical safety	IEC60601- 1	IEC 60601- 1
	Thermal safety	IEC 60601- 1	IEC 60601- 1
	EMC safety	IEC60601-1-2	IEC60601-1-2

1.9.3. Comparison discussion

The topics of the design modifications are presented below:

Hardware modifications:

The predicate device Duet DRF K103038 was slightly modified:

1. Predicate device Duet DRF K103038 supports a dynamic Pixium RF 4343 FPD (Flat Panel Detector). The modified device ArtPix DRF also supports the same FPD as the predicate device. Alternatively, a few more dynamic FPD models were integrated into modified ArtPIX DRF.
    a. Pixium 4343 FL
    This FPD is manufactured by the same manufacturer of RF 4343 FPD (Thales from France) used in the predicate device. It has been cleared by FDA in the currently marketed (K160301) Platinum dRF Imaging System. It has almost same performance of the RF 4343 used in the predicate Duet DRF, with a slightly lower fluoroscopy acquisition rate.
    b. Pixium 4343 FL Model 4
    This FPD is manufactured by the same manufacturer of RF 4343 FPD (Thales from France) used in the predicate device. It is using the same technology and has almost same performance of the RF 4343 used in the predicate Duet DRF.
    c. Pixium 2121S-A
    This FPD is also manufactured by the same manufacturer of RF 4343 FPD (Thales from France) used in the predicate device. It is using the same technology and has almost same performance of the RF 4343 used in the predicate Duet DRF. This new model covers a smaller area compared to the RF 4343 FPD used in the predicate device, thus allowing a more cost effective solution for clinical sites that do not require approximately 43 x 43 cm of area coverage. The 2121S-A allows an effective area of approximately 21 x 21 cm.
    d. Pixium 3030S-A
    This FPD is also manufactured by the same manufacturer of RF 4343 FPD (Thales from France) used in the predicate device. It is using the same technology and has almost same performance of the RF 4343 used in the predicate Duet DRF. This new model covers a smaller area compared to the RF 4343 FPD used in the predicate device, thus allowing a more cost effective solution for clinical sites that do not require approximately 43 x 43 cm of area coverage. The 3030S-A allows an effective area of approximately 30 x 30 cm.

    Comparison of the FPDs is shown in section 1.9.2.

2. An optional static Portable Flat Panel Detector was added to the modified ArtPIX DRF device. It allows technicians to work closely with patients even under the most demanding circumstances. The FPD used is part of the 3543EZ or 2430EZ family of Portable Flat Panel Detectors. These detectors have been cleared by FDA in the currently marketed (K162224) CMT Medical Technologies ArtPIX Mobile EZ2GO system.
3. The Duet DRF K103038 PC was replaced by a newer and more powerful computer. In

terms of technical performance (Processing Capabilities, Display), the new PC is no worse than the PC used in Duet DRF.
The proprietary Allegro input card used for real-time image processing in the predicate device was replaced by a GPU board.
The proprietary Accord analog display card of the predicate device was replaced by digital output displays in the modified device.
There is no impact on the fundamental scientific technology, indication for use, safety and effectiveness.

4. The RCU (Room Control Unit) used in the predicate Duet DRF K103038 was replaced by a up-to-date designed unit. The modified unit supports all functions of the predicate device (x-ray generator interface, ABC interface).
5. The isolation transformer used inside the RCU of the Duet DRF K103038 predicate device was replaced by a newer isolation transformer, boxed separately outside the unit. There is no impact on the fundamental scientific technology, indication for use, safety and effectiveness.
6. The keypad used in the predicate Duet DRF K103038 was replaced by a tablet computer. There is no impact on the fundamental scientific technology, indication for use, safety and effectiveness.
7. The power supply for the Flat Panel Detector used in the predicate Duet DRF K103038 inside the FPU (Flat Panel Supply Unit) was replaced by a newer one and placed inside the ORION unit in the modified ArtPIX DRF. There is no impact on the fundamental scientific technology, indication for use, safety and effectiveness.

Software modifications:

The software basic functions were not changed. The control of the ArtPIX DRF system, like the control of its predicate device, is based on embedded software and includes the same basic features: Status control, Man Machine Interface (MMI), Image acquisition, display, processing, storage and DICOM communication.
User interface was changed in order to be up-to-date with the modern applications.
Additional code was incorporated to support the dynamic FPDs Pixium 4343 FL, Pixium 4343 FL Model 4, Pixium 2121S-A, Pixium 3030S-A, as well as the optional static portable detectors Pixium (3543EZ / 2430EZ/3543DR family).
Both the Predicate K103038 Duet DRF and the ArtPIX DRF use similar FPD calibration scheme. It consists of preparation of the calibration tables and of the real-time application of the corrections.
Additional DICOM communication functions (RDSR, Storage Commitment and MPPS) were added in the modified device ArtPix DRF. DICOM Print function which is hardly used in US facilities has been removed from the modified device ArtPix DRF.
Post processing supporting code was added. General radiography image processing algorithms and code, which have been cleared by FDA in the currently marketed (K162224) CMT Medical Technologies' ArtPIX Mobile EZ2GO system were added in the modified device. The real time image processing algorithms for fluoroscopic and spot filming implemented by hardware in the predicate device Duet DRF K103038 were replaced by compatible software in the modified ArtPIX DRF device.
The submitted device description includes enhanced connectivity, processing time, convenience

of use, production ability, and serviceability.
There is no impact on the fundamental scientific technology, indication for use, safety and effectiveness.
A stitching feature was added to the modified ArtPIX DRF device, as part of the radiology routine. It does not change the intended use of the device. This feature allows to combine 2-5 static images into a single long leg and spine long images. The whole stitching process is user controlled: the user selects the constituent images, activates the stitching algorithm, approves the resulting stitched image and archives it. Whenever needed, the user has the ability to readjust the stitched image by manually shifting the constituent images relative to one another. Further, every change of the resulting stitched image has to be approved by the user before being saved.

Summary: This submission presents design changes. The modified device ArtPix DRF is compared to the predicate Duet DRF K103038. It has the same intended use. The changed device has almost the same technological and performance characteristics of the predicate devices 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 that demonstrate that the device is substantially equivalent to the predicate device.

1.10. Verification, Validation (V&V)

The V&V processes of the modified ArtPIX DRF have been performed 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 DRF 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. Software anomalies that were detected during this stage were recorded to and corrected.
d. The system performance of the modified ArtPix DRF was validated by measuring the image quality.
e. RMF and System Requirements were tested. All unresolved anomalies have been recorded. None of them impacts the safety, performance and effectiveness of the modified ArtPIX DRF

Conclusion:
The modified ArtPix DRF system passed its acceptance criteria and is recommended for release.