MedicaTech USA
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

April 25, 2019

Re: K190601
Trade/Device Name: MasteRad MX30
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: March 29, 2019
Received: April 2, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190601

Device Name
MasteRad MX30

Indications for Use *(Describe)*
The MasteRad MX30 is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

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, 510(k) K190601

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Contact: George Makar, Predsident
Date Prepared: January 23, 2019

1. **Identification of the Device:**
   Trade/Device Names: MasteRad MX30
   Regulation Number: 21CFR892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: II
   Product Code: KPR and MQB
   Common/Usual Name: Stationary Digital Diagnostic X-Ray System

2. **Equivalent** legally marketed device: K143257
   Trade/Device Name: KrystalRad 1100 and KrystalRad 3000
   Manufacturer: MedicaTech USA
   Regulation Number: 21CFR892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: II
   Product Code: KPR and MQB
   Common/Usual Name: Stationary Digital Diagnostic X-Ray System

3. **Indications for Use** The MasteRad MX30 is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

4. **Description of the Device**: This device represents a new combination of already cleared solid state digital x-ray acquisition panels (plus one NEW panel) and software with the diagnostic x-ray compnents required to make a complete system. The purchaser may select their digital panel from this list:.

Manufacturer Model Number	MedicaTech Model Number	510(k) Number
Varex PaxScan 2530Wv4	Master X CW25	K161459
Varex PaxScan 4336Wv4	Master X CW36	K161459
Varex PaxScan 4343R	Master X FC43	K172951
Varex PaxScan 4343RC	Master X PT43	K172951
Varex XRpad 4343F	Master X HDF43	K142698
Varex XRpad 3025	Master X WPH25	K161942
Varex XRpad 4336	Master X WHD36	K161966
Toshiba* FDXA4343R	Master X FA43	New

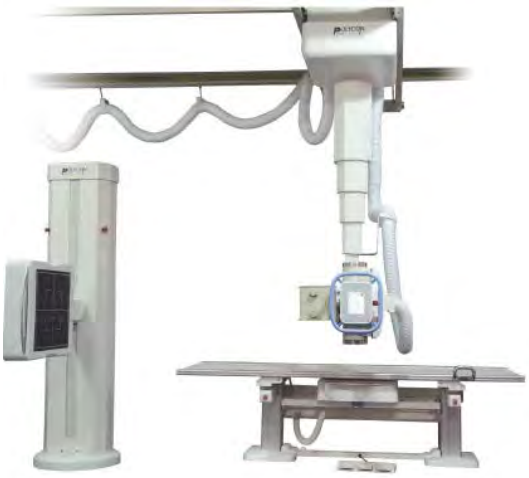
As compared to our predicate system, the tube stand is floor mounted instead of ceiling mounted. The collimator is different. Instead of the Ralco collimator, a Collimare model is supplied. The purchaser selects one of the following FDA certified models: CML-150-0001-C; CTL-150-0001-C; CML-125-0001-C. The x-ray tube and the high voltage generator remains the same as our predicate. The x-ray tube is a Toshiba model and the generator is the CPI CMP 200DR.
The image acquisition software is a newer version of our Voyance software originally cleared in K130377

The system complies with the CDRH Radiological Health performance standard in the Code of Federal Regulations, as well as the voluntary IEC standards IEC 60601-1 and IEC 60601-1-2.
*Toshiba panel division has recently been purchased by Canon.

5. **Safety and Effectiveness, comparison to predicate device**. This combination device has the same indications for use and very similar technological characteristics as the predicate device, and employs already 510(k) cleared digital panels (except for the Toshiba unit) and software.

6. **Substantial Equivalence Chart:**

Characteristic	**K143257 KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems**	**MastRad MX30**
Indications for Use:	The KrystalRad Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.	MasteRad MX30 is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography. SAME
Configuration of Digital Panels	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet (depending on the model chosen) SAME
Digital Panel Models	Vieworks FXRD-1717SA/SB, or Vieworks FXRD-1417SA/SB or Vieworks FXRD-1417WA/WB or Toshiba: FDX4343R/RPW or Toshiba FDX3543RP/RPW or Varex XRpad 4336	Varex PaxScan 2530Wv4 or Varex PaxScan 4336Wv4 or Varex PaxScan 4343R or Varex PaxScan 4343RC or Varex XRpad 4343F or Varex XRpad 3025 or Varex XRpad 4336 or Toshiba (Now Canon) FDXA4343R
DICOM	DICOM 3	SAME

Characteristic	K143257 KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems	MastRad MX30
Image acquisition software	Voyance	Voyance. Updated.
Power Source	AC Line, various voltages available	SAME
Photo	Krystalrad 3000 	MasteRad MX30  Difference: Floor Mount instead of Ceiling Mount.
Generator	CPI CMP 200DR	SAME
X-Ray Tube	Toshiba	SAME
Collimator	Ralco R301A	Collimare LLC, one of the following FDA certified models: CML-150-0001-C, CTL-150-0001-C, CML-125-0001-C

A new digital x-ray receptor panel not previously cleared by FDA is offered. The predecessor to this panel was cleared in K130883. The characteristics are compared in the table below. The images were evaluated by a Board Certified Radiologist, and found to be of diagnostic quality.

Characteristic	Sedecal Digital Radiogniphic Upgrade Model SDRU-T K130883 (Toshiba Model FDX4343R)	Toshiba Model FDXA4343R (One of the available models for MasteRad.
Image Format		
X-ray Conversion Layer	Cesium Iodide (CsI) with Amorphous Silicon (a-Si) Photodiode	SAME
Active Area	430(H)×439(V)mm (16.9×17.3 inch)	426 (H)×425 (V) mm (16.8×16.7 inch) (Not a meaningful difference)
Pixel Matrix	3008(H)×3072(V)	3040 (H)×3036 (V) (Not a meaningful difference)
Pixel Pitch	143 µ m	140 µm (Not a meaningful difference)

Characteristic	Sedecal Digital Radiogniphic Upgrade Model SDRU-T K130883 (Toshiba Model FDX4343R)	Toshiba Model FDXA4343R (One of the available models for MasteRad.
Cycle Time	Shot to Shot 6sec	Shot to Shot 6sec No difference
Performance		
Limiting Resolution	3.5 Lp/mm typ	3.7 Lp/mm Max. Slightly better
MTF (2.0 Lp/mm, 70 kVp, 1×1)	36 % Typ	50 % typ Slightly better
DQE (0), Quantum - Limited	> 70 %	> 56 % (Typ.) (Not a meaningful difference. Images found to be of diagnostic quality, however)
A/D Conversion	14 bit	16 bit Slightly better

7. **Summary of non-clinical testing**: We performed software validation and risk management for the updated software version. The following FDA guidances were employed in those activities: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* and *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.* The software comlies with NEMA PS 3.1 - 3.18 (2009) Digital Imaging and Communications in Medicine (DICOM) Set. We revised our labeling in light of the FDA guidance: *Pediatric Information for X-ray Imaging Device Premarket Notifications.* We performed integration testing to show that each panel performed correctly in the full system. The device conforms to US Performance Standards and the hardware is UL Listed to US Standards for safety for medical devices (UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety standard by Underwriters Laboratories, 04/25/2003.) There is one new digital receptor panel, and we were provided test information per *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016* The software comlies with NEMA PS 3.1 - 3.18 (2009) Digital Imaging and Communications in Medicine (DICOM) Set. The results of a review of bench, safety test, and software validation documentation indicates that the new device is as safe and effective as the predicate device

8. **Summary of clinical testing**: Clinical images are not required for the previously cleared panels, but the new Toshiba panel has not previously received FDA clearance. Clinical images were acquired from the new Toshiba panel panel and reviewed by a board certified radiologist, as recommended in the FDA document: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging* Devices The images were found to be of excellent diagnostic quality.

9. **Conclusion:** After analyzing software integration validation, safety testing data, and clinical images, it is the conclusion of Medicatech USA that the "MedRad" system is as safe and effective as the predicate device, has insignificant technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate device.