September 1, 2023

Medicatech USA
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K230918
Trade/Device Name: MasterX 800 Series
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: August 7, 2023
Received: August 7, 2023

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological 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)*

K230918

Device Name
MasterX 800 Series

Indications for Use *(Describe)*

The MasterX 800 Series is intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the MasterX 800 Series is intended to acquire digital radiographic images on adult and pediatric patients. It is suitable for all routine radiography exams, including specialist areas like intensive care or trauma work, excluding fluoroscopy, angiography and 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) K230918

Submitter: MedicaTech USA
50 Maxwell
Irvine , CA , 92618
Toll Free : +1 800 817 5030
Phone : +1 949 679 2881
FAX : +1 949 679 2882
Registration Number 3004989804
Contact: George Makar, Predsident
Date Prepared: August 25, 2023

1. **Identification of the Device:**
   Trade/Device Names: MasterX 800 Series
   Regulation Number: 21CFR 892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: II
   Product Code: MQB
   Common/Usual Name: Digital Diagnostic X-Ray System Upgrade

2. **Equivalent** legally marketed device: K130377
   Trade/Device Name: KrystalRad "New Series" Radiographic Portable Retrofit
   Manufacturer: MedicaTech USA
   Regulation Number: 21CFR892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: II
   Product Code: MQB
   Common/Usual Name: Digital Diagnostic X-Ray System Upgrade

3. **Reference Devices:** Uses software cleared in our 510(k) number K190601, but updated. Uses one of the following previously cleared digital receptor panels, supplied unmodified:

lnnoCare Model Name Yushan *Series*	510(K) numbers	Product code/regulation
Yushan V14C/ Yushan V14G/ Yushan V17C/ Yushan V17G/ Yushan V17Ge	K201528	MQB/21CFR892.1680
Yushan F14C/ Yushan F14G	K210988	MQB/21CFR892.1680
Yushan V17Ce	K220510	MQB/21CFR892.1680

4. **Indications for Use** The MasterX 800 Series is intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the MasterX 800 Series is intended to acquire digital radiographic images on adult and pediatric patients. It is suitable for all routine radiography exams, including specialist areas like intensive care or trauma work, excluding fluoroscopy, angiography and mammography.

5. **Description of the Device**: This device represents a new combination of already cleared solid state digital x-ray acquisition panels and already cleared software. It is suitable for use with adult and pediatric populations. This is an upgrade kit for existing or new systems.

The purchaser may select their digital panel from this list:

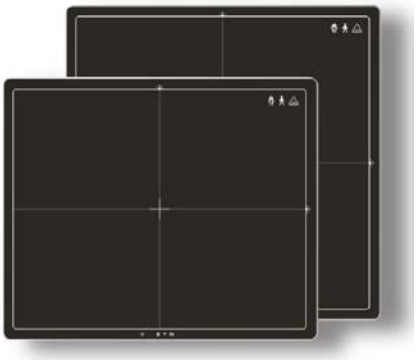
lnnoCare Model Name Yushan *Series*	MedicatechUSA Model Name Masterx80XX	510(K) number	Size and Description
Yushan V14C	MasterX80lC	K201528	14X17 Csi Wireless Panel (Can work as Tethered)
Yushan V14G	MasterX801G	K201528	14X17 GOS Wireless Panel (Can work as Tethered)
Yushan F14C	MasterX802C	K210988	17X17 Csi Wireless Panel (can work as Tethered)
Yushan F14G	MasterX802G	K210988	17Xl7 GOS Wireless Panel (can work as Tethered)
Yushan V17C	MasterX803C	K201528	Glassless 14X17 Csi Wireless Panel (Can work as Tethered)
Yushan V17G	MasterX803G	K201528	Glassless 14X17 GOS Wireless Panel (Can work as Tethered)
Yushan V17Ce	MasterX804Ce	K220510	17X17 Csi Fixed Tethered Panel
Yushan V17Ge	MasterX804Ge	K201528	17X17 GOS Fixed Tethered Panel

As compared to our predicate system, the digital panels are more recently cleared by FDA. The image acquisition software is our Voyance software most recently cleared in K190601.
The digital panels all comply with the voluntary IEC standards IEC 60601-1 and IEC 60601-1-2.

6. **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.

7. **Substantial Equivalence Chart:**

Item	K130377 KystalRad "New Series" Radiographic Portable Retrofit	MasterX 800 Series	Comment
Indications for Use:	Intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the KrystalRad "New Series" is intended td acquire digital radiographic images. It is suitable for all routine radiography exams, including specialist areas like intensive care or trauma work, excluding fluoroscopy, angiography and mammography.	The MasterX 800 Series is intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the MasterX 800 Series is intended to acquire digital radiographic images on adult and pediatric patients. It is suitable for all routine radiography exams, including specialist areas like intensive care or trauma work, excluding fluoroscopy, angiography and mammography.	Patient population added.
Configur-ation of Digital Panels	Battery or AC operated wireless IEEE ac/a/g/n or Wired Ethernet (depending on the model chosen)	Battery or AC operated wireless IEEE ac / a/g/n or Wired Ethernet (depending on the model chosen)	Exactly the same.
Power Source	AC Line or Rechargeable Battery Battery life up to 8 hours	AC Line or Rechargeable Battery Battery life up to 8 hours Some models use AC Line only. See chart above.	SAME

Item	K130377 KystalRad "New Series" Radiographic Portable Retrofit	MasterX 800 Series	Comment
Digital Panel Models	Vieworks Vivix-S K122866 or Vivix-S Wireless K122865	8 new models from InnoCare, see list in paragraph 5, above.	Newer models
Panel Performance	DQE @ 1lp/mm : 50 % MTF @ 1lp/mm : 60 %	DQE at 1 lp/mm, 50% MTF @ 1 lp/mm, 63%	Similar
Interface	Tethered or Wireless	Tethered or Wireless (See table above)	SAME
Photo (example)			Similar appear-ance.
Panel sizes	14” x 17” or 17” x 17”	SAME sizes are available.	SAME
X-ray Conversion Layer	Cesium Iodide (CsI) with Amorphous Silicon (a-Si) Photodiode	Csi OR GOS (GOS is lower cost but has nearly comparable peformance)	SAME
Active Areas	Wired panel pixels: 2,560 x 3,072, or 3,072 x 3,072 or Wireless panel pixels 2560 x 3072	MasterX80IC/G: 2500 x 3052 MasterX802C/G: 2500 x 3052 MasterX803C/G: 3072 x 3072 MasterX804Ce/Ge: 3072 x 3072 (wired only)	Nearly identical
Pixel pitch	140 µm	140 µm	SAME
A/D Conversion	14 Bits	All the new panels have 16 bit conversion	Better
Image acquisition software	Voyance	Voyance	SAME
DICOM	DICOM 3	DICOM 3	SAME

8. 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. Our labeling reflects 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 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

9. **Summary of clinical testing**: Not required.

10. **Conclusion:** After analyzing software integration validation, safety testing data, and test MasterX 800 Series images, it is the conclusion of Medicatech USA that the MasterX 800 Series 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.