510(K) Summary, 510(k) K130377

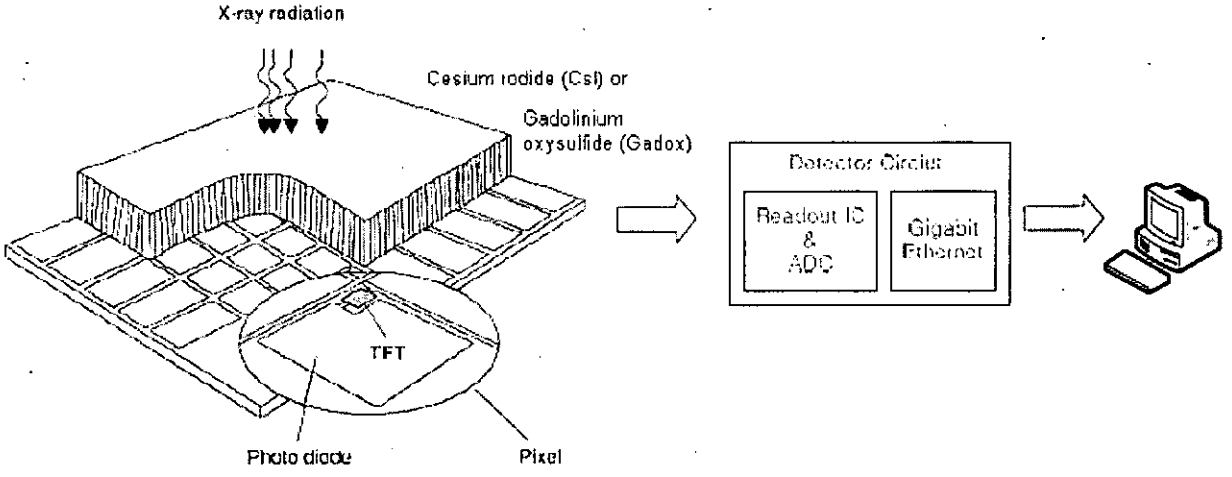
MAY 17 2013

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: March 27, 2013

1. **Identification of the Device:**
   Proprietary-Trade Name: **KrystalRad "New Series" Radiographic Portable Retrofit System**
   Classification Name: Solid state x-ray imager (flat panel/digital imager), MQB
   Common/Usual Name: Digital X-Ray Panel

2. **Equivalent legally marketed devices**: K112132, KrystalRad 660, MedicaTech USA. The modified device represents the combination of already cleared devices.

3. **Description of the Device**: This device represents the combination of already cleared software and already cleared digitan receptor panels.
   a) How the device functions. This device is a functional replacement for radiographic film. It serves as an upgrade to film based or older digital panel diagnostic x-ray systems. Digital radiography uses digital X-ray sensors instead of traditional photographic film. Advantages include time efficiency through bypassing chemical processing and the ability to digitally transfer and enhance images. Also less radiation can be used to produce an image of similar contrast to conventional radiography. This gives advantages of immediate image preview and availability; elimination of costly film processing steps; a wider dynamic range, which makes it more forgiving for over- and under-exposure; as well as the ability to apply special image processing techniques that enhance overall display of the image.
   b) Scientific concept forming the basis of the device.



The Thin Film Transistor (TFT) Panel accumulates the visible ray (rendered visible by the scintillator, which is transformed from X-ray by the scintillator, at the photodiodes. The accumulated photic signal in the photodiode is output by readout Integrated Circuit (ROIC) anddisplayed after an Analog to Digital Convertor (ADC) transforms photic signal to digital signal.When the detector receives a signal from X-ray high voltage generator, it converts cumulated

signal to 14-bit digital images at detector circuit and transmits those images to the workstation using the Gigabit Ethernet. The workstation receives images then handles them with software to display on the monitor and to save data in the hard disk.
c) Significant physical and performance characteristics: This device is functionally identical to our recent submission K112132, a wireless digital upgrade to existing film systems. A wired panel is also available. We have changed the wireless panel to another model of a nearly identical size and resolution (already cleared). We have changed the software to the 510(k) cleared package from K103554, now sold under the trade name Voyance-M. The upgrade should be installed by a qualified trained field engineer. Alternately we still offer the original software package, the Modern Module Omnivision.

4. **Indications for Use** (intended use): Intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the KrystalRad "New Series" is intended to 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..

5. **Safety and Effectiveness, comparison to predicate device**. This combination device has the same indications for use and technological characteristics as the predicate devices, in fact employing already cleared devices in the end product.

6. **Substantial Equivalence Chart**

Comparison Chart, KrystalRad "New Series," MedicaTech USA

Characteristic	**K112132, KrystalRad 660, MedicaTech USA**	**KrystalRad "New Series," MedicaTech USA**
Explanation	This is the device we have MODIFIED with new panels and software	This device represents the combination of already cleared devices, PACS software and digital x-ray panels.
Intended Use:	Intended to 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	SAME as KrystalRad 660, unchanged.
Configuration	Battery operated wireless or Wired Ethernet	Battery operated wireless or Wired Ethernet
Image acquisition panel specifications	Wireless panel 2400 by 3000 pixels Pitch: 144 μm Bit depth 14 bit	Wired panels: 2,560 x 3,072 pixels 3,072 x 3,072 pixels or Wireless panel 2560 x 3072 pixels Pitch: 140 μm Bit depth 14 bit.
Identification of the Panels	PIXIUM 3543 pR	Vieworks Vivix-S K122866 or Vivix-S Wireless K122865
Communication Standard	IEEE 802.11n (2.4 GHz) or hardwire Ethernet	IEEE 802.11n (2.4 GHz) or hardwire Ethernet
DICOM	DICOM 3	DICOM 3
Image acquisition software	Same as: K080582 DDR MAK Series Medicatech USA (E-Com) – OR- K110040 OmniVision, Modern Module Inc	Same as: K103554 Metron MD, EponaTech LLC, rebranded Voyance-M OR OmniVision, K110040 made by Modern Module Inc

K130377

Characteristic	K112132, KrystalRad 660, MedicaTech USA	KrystalRad "New Series," MedicaTech USA
Communication	WiFi or hardwire	SAME
Image Dimensions	14 x 17 in. (35 x 43 cm) / 17 x 17 in. (43 x 43 cm)	14 x 17 in. (35 x 43 cm) / 17 x 17 in. (43 x 43 cm)
Weight	4.7 kg	6.3 lbs (2.9 kg / GOS) & 6.8 lbs.(3.1 kg / CsI) Wireless: 6.8 lbs (3.1 kg / GOS) & 7.2 lbs.(3.3 kg / CsI) 17 x 17 in. Fixed: 24.2 lbs (11 kg / GOS) & 24.2 lbs.(11 kg / CsI)
Electrical safety	Electrical Safety per IEC-60601. UL listed	Electrical Safety per IEC-60601. UL listed

7. **Summary of non-clinical testing**: We performed integration testing. The results of a review of bench, safety test, and software validation documentation indicates that the new device is as safe and effective as our predicate device. The modified device conforms to US Performance Standards and the hardware is UL Listed to US Standards for safety for medical devices. Standards testing performed included:
    a. IEC 60601-1 (1988) +IEC 60601-1 Amendment 1 (1991); +IEC 60601-1 Amendment 2 (1995) Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety
    b. IEC 60601-1-2 Collateral standard: Electromagnetic compatibility –Requirements and tests
    c. NEMA PS 3.1 - 3.18 (2009), Digital Imaging and Communications in Medicine (DICOM) Set.

8. **Summary of clinical testing**: Clinical images were acquired and compared to our predicate images by a board certified radiologist. There were no significant differences between them. 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 KrystalRad "New Series" is as safe and effective as the predicate devices, have almost no technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate devices.

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

May 17, 2013

Medicatech USA
C/O Daniel Kamm, P.E.
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

Re: K130377
Trade/Device Name: KrystalRad "New Series" Digital Radiographic Portable Retrofit System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: II
Product Code: MQB
Dated: April 1, 2013
Received: April 5, 2013

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. 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.

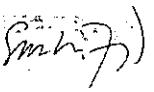
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130377

Device Name: KrystalRad "New Series" Digital Radiographic Portable Retrofit System

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 to 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.

Prescription Use _X_	AND/OR	Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k): K130377