K112132

NOV 18 2011

510(K) Summary, 510(k) K11

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Date Prepared: July 10, 2011

1. **Identification of the Device:**
   Proprietary-Trade Name: **KrystalRad 660 Digital 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:**
   - The image processing software is the same as provided in our 510(k) K080582 DDR MAK Series. Alternately the image processing software is the same as in OmniVision, K1100403 made by Modern Module Inc.
   - The Detector is identical to the Wireless Portable Detector FD-W17 (K090625) marketed by Philips Medical Systems

3. **Description of the Device**: This device is simply the combination of two cleared devices, the same Wireless Portable Detector as used in the FD-W17 (K090625) marketed by Philips Medical Systems and the image processing software cleared in our K080582 DDR MAK Series. Alternately the image processing software is the same as in OmniVision, K1100403 made by Modern Module Inc. The Wireless Portable Detector consists of three main parts: Portable radiography detector (x-ray sensitive part); Docking station which is directly connected to the radiographic workstation and a backup cable which can connect the detector to the docking station if the wireless connection cannot be used. Detector size: 35 x 43 cm (14 x 17") Image matrix size: 3000 pixels x 2400 pixels. Pixel size 144 µm, Image resolution up to 3.5 LP/mm. The device is intended as an upgrade to existing film x-ray systems. It should be installed by a qualified trained field engineer.

4. **Indications for Use** (intended use): Intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the KrystalRad 660 is intended to acquire digital radiographic images. It is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric 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 the predicate devices in the end product.

6. **Description of Testing:** Clinical images were acquired and compared to our predicate images. There were no significant differences between them. We also performed integration testing. The results of a review of clinical, 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.

7. Substantial Equivalence Chart

Characteristic	Philips Wireless Portable Detector FD-W17 K090625	KrystalRad 660
Intended Use:	As a part of a radiographic system, the Wireless Portable Detector FD-W17 is intended to acquire digital radiographic images. The Wireless Portable Detector FD-W1 7 is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.	Intended for use by a qualified/trained doctor or technologist. As part of a radiographic system, the KrystalRad 660 is intended to acquire digital radiographic images. It is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.
Configuration	Battery operated wireless	SAME
Performance Standard	21 CFR 1020.30	SAME
Image acquisition panel	PIXIUM PORTABLE 3543	SAME
Image acquisition software	Philips XD-S workstation (K063781)	Same as: K080582 DDR MAK Series Medicatech USA (E-Com) – OR- K110040 OmniVision, Modern Module Inc.
Communication	WiFi or hardwire	SAME
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

8. **Conclusion:** After analyzing software integration validation, safety testing data, and clinical images, it is the conclusion of Medicatech USA that the KrystalRad 660 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
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Medica Tech USA
% Mr. Daniel Kamm, P.E.
Regulatory Engineer, Submission Correspondent AUG 23 2013
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K112132
Trade/Device Name: KrystalRad 660 Digital Radiographic Portable Retrofit System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 17, 2011
Received: October 20, 2011

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of November 18, 2011.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112132

Device Name: KrystalRad 660 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 660 is intended to acquire digital radiographic images. It is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric 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 Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K112132