



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

September 18, 2014

MinXray, Inc.  
% Mr. Daniel Kamm  
Principal Engineer  
Kamm & Associates  
8870 Ravello Court  
NAPLES FL 34114

Re: K141885

Trade/Device Name: CMDR-2ST & CMDR-2SLWT Digital Portable X-ray System  
Regulation Number: 21 CFR 892.1720  
Regulation Name: Mobile x-ray system  
Regulatory Class: II  
Product Code: IZL, MQB, LLZ  
Dated: August 15, 2014  
Received: August 19, 2014

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 Industry and Consumer Education 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” (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 Industry and Consumer Education 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)

K141885

Device Name

CMDR-2ST & CMDR-2SLWT

Indications for Use (Describe)

This digital radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. (Not for mammographic 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**510(k) Summary: 510(k) Number K141885**

**MinXray, Inc.**

**3611 Commercial Avenue**

**Northbrook, Illinois 60062, USA**

**Toll Free 1-800-221-2245 (USA & Canada)**

**Tel. 1-847-564-0323**

**Fax 1-847-564-9040**

**Date Prepared: August 15, 2014**

**Contact: Keith Kretchmer, President**

**1. Identification of the Device:**

**Proprietary-Trade Name: CMDR-2ST & CMDR-2SLWT** Digital Portable X-ray System

**2. Classification Name:** Mobile x-ray system, Product Code 90 IZL and Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB, Picture Archiving and Communications System 90 LLZ.

**Common/Usual Name:** Digital Mobile Diagnostic X-Ray System

**Regulation Number:** 21 CFR 892.1720

**3. Equivalent legally marketed device:** MinXray CMDR-2S, K100449

**4. Indications for Use (intended use):** This digital radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammographic use.

**5. Description of the Device:** This represents the straightforward interconnection of three devices: The MinXray HF120/60H PowerPlus™ (K040046), the Toshiba Solid State Imager, and the dicomPACS® software package. MinXray HF120/60H PowerPlus™ is a portable unit which operates from 120 V 50-60~ AC. The generator unit utilizes a high frequency inverter and can be mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator. The digital panel features the Toshiba flat panel technology in a sleek and compact unit. The portable panel provides digital X-ray image capture for a wide range of applications. The lightweight design, generous imaging area, and fast processing times of the detector make it easy to capture high quality diagnostic images for routine diagnosis, as well as challenging trauma and bedside exams. It's a portable solution for a faster, more streamlined approach to digital radiography. The only difference between this modified device and our predicate device is the supplier of the digital x-ray receptor panel. The previous supplier was Varian. The two model numbers differ only in the configuration and weight of the mounting hardware.

**6. Safety and Effectiveness, comparison to predicate device.** The results of bench testing indicates that the new device is as safe and effective as the predicate devices. Proper system operation is fully verified upon installation. We verified that the modified combination of components worked properly and produced diagnostic quality images as good as our predicate generator/panel combination.

**7. Substantial Equivalence Chart**

Characteristic	MinXray CMDR-2S Digital Diagnostic X-Ray System K100449	CMDR-2ST & CMDR-2SLWT
Intended Use:	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography	SAME
Configuration	Mobile System	SAME
Computer	Dell laptop	SAME

Characteristic	MinXray CMDR-2S Digital Diagnostic X-Ray System K100449	CMDR-2ST & CMDR-2SLWT
Generator	High Frequency HF120/60H PowerPlus™	SAME
Digital X-ray Panel Supplier	Varian 4336R	Toshiba FDX3543RP
Panel Performance	Pixel size 139 x 139 μm Matrix size 2,560 x 3,072 Size 14" x 17"	Pixel size 143 x 143μm Matrix size 2448x2984 Size 14" x 17"
Panel Interface	Ethernet	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	Uses high frequency generator made by Mikasa X-Ray in Japan. 80 khz.	SAME generator
PACS software	dicomPACS®	dicomPACS®
Power Source	120 V 50/60 Hz AC 20 amp	SAME
Digital Panel		

- 8. Summary of non-clinical testing:** A prototype system was assembled and tested. First the dicomPACS® software was installed on the Dell Inspiron laptop computer. The proper installation was verified by running the software. Next, the synchronization circuit was connected between the Mikasa HF portable generator and the Toshiba panel. The Ethernet cable was then connected between the Toshiba panel and the Dell laptop. The panel was connected to the AC power source and turned on. Then the Mikasa HF portable generator was turned on. The Mikasa generator was set to generate an exposure. The generator was aimed at the Toshiba panel, and a radiographic phantom was placed on the panel. Several test exposures showed that the system was operating properly. No modifications were necessary to any of the hardware or software other than changing the digital panel. The completed system complies with DHHS radiation safety standards currently in effect, i.e. 21 CFR 1020.30 and 21 CFR 1020.31 and has undergone testing for compliance with UL 60601-1 (Electrical medical device safety), IEC 60601-1-2 (Electromagnetic Compatibility). The software was tested to and complies with the NEMA PS 3.1-3.20(DICOM) standard. The Toshiba detector has been previously cleared under K131211.
- 9. Summary of clinical testing:** Because this same Toshiba panel/software combination has been cleared by FDA before, a full clinical trial per the FDA guidance document on solid state imaging devices was deemed to be unnecessary, per the FDA "Least Burdensome" guidance. Instead we employed "Supertech" lung/chest phantom and other phantoms to obtain images from both the predicate and the new digital panel. The images were evaluated by a board certified radiologist and found to be of comparable diagnostic quality.
- 10. Conclusion:** After analyzing bench and clinical tests, it is the conclusion of MinXray Inc. that the CMDR-2ST & CMDR-2SLWT Digital Diagnostic X-Ray System is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.