DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 7, 2017

MinXray, Inc.
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

Re: K171353
Trade/Device Name: CMDR 2ST (Multiple Models), CMDR 2SPE (Multiple Models), Integris
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB, LLZ
Dated: May 3, 2017
Received: May 9, 2017

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,

For

Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171353

Device Name
CMDR 2ST (Multiple Models), CMDR 2SPE (Multiple Models), Integris

Indications for Use *(Describe)*
Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. 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) Number K171353

MinXray, Inc.
3611 Commercial Avenue
Northbrook, Illinois 60062, USA
Toll Free 1-800-221-2245 (USA & Canada)
Date Prepared: May 27, 2017
Contact: Keith Kretchmer, President

1) **Identification of the Device:**
Trade/Device Name: CMDR 2ST (Multiple Models), CMDR 2SPE (Multiple Models), Integris
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Codes: IZL, MQB, and LLZ.
Common/Usual Name: Digital Mobile Diagnostic X-Ray System

2) **Equivalent legally marketed device**: **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 Codes: IZL, MQB, and LLZ.
Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3) **Reference devices** (We employ these cleared devices without modification):
   a) Trade/Device Name: K140551 Perkinelmer, XRpad 4336 MED Flat Panel Detector
   Regulation Number: 21 CFR 892. 1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Code: MQB
   b) Trade/Device Name: K141440; Oehm Und Rehbein Gmbh, DicomPACS® DX-R with flat panel
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary X-ray System
   Regulatory Class: Class II
   Product Code: MQB

4) **Indications for Use (intended use):** These digital radiographic systems are 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 combination of three devices:
One of three cleared MinXray Portable HF X-ray generators:
HF120/60H PowerPlus cleared in K040046, (and in K141885) **OR** HF100H+ cleared in K052721 **OR**
HF1202 PowerPlus cleared in K153059.
One of three cleared digital X-ray receptor panels:
Toshiba FDX3543RP **OR** the Toshiba FDX3543RPW cleared in K162687 (and others) **OR** the
PerkinElmer Solid State Imager, (K140551)
PLUS: the dicomPACS® software package (K141885) (Same as our predicate).
The X-ray generators are portable units which operate 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 either the formerly used Toshiba panels or PerkinElmer flat panel technology in a sleek and compact unit. The portable panels provide 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. .

6) Substantial Equivalence Chart

Characteristic	Predicate: CMDR-2ST & CMDR-2SLWT Digital X-Ray System K141885	CMDR 2ST (Multiple Models)	CMDR 2SPE (Multiple Models)	Integris
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	SAME	SAME
Configuration	Mobile System with digital x-ray panel and image acquisition computer	SAME	SAME	SAME
Computer	Dell laptop	Dell Precision M3510 or Dell Latitude 14 (ruggedized)	Dell Precision M3510 or Dell Latitude 14 (ruggedized)	Beckhoff C6920/C6925
X-ray Generator(s) (All made by Mikasa X-Ray)	HF120/60H PowerPlus (K040046)	SAME OR HF100H+ (K052721) HF1202H PowerPlus (K153059)	SAME OR HF100H+ (K052721) HF1202H PowerPlus (K153059)	HF1202H PowerPlus (K153059)
Basic Generator Character-istics	120 VAC Line operated HF120/60H PowerPlus™ produces up to 120 kVP and 2.4 kW peak	SAME OR HF100H+: up to 100 kVp and 2 kW peak HF1202H PowerPlus: up to 120 kVp up to 3.0 kW peak	SAME OR HF100H+: up to 100 kVp and 2 kW peak HF1202H PowerPlus: up to 120 kVp up to 3.0 kW peak	HF1202H PowerPlus: up to 120 kVp up to 3.0 kW peak
Collimator	Collimare LED Collimator	Collimare LED Collimator	Collimare LED Collimator	Collimare LED Collimator

Characteristic	Predicate: CMDR-2ST & CMDR-2SLWT Digital X-Ray System K141885	CMDR 2ST (Multiple Models)	CMDR 2SPE (Multiple Models)	Integris
Generator Photo(s)	HF120/60HPPWV PowerPlus 	HF120/60HPPWV PowerPlus  OR: HF100H+  OR: HF1202H PowerPlus 	CMDR 2SPE 120/60 PP  OR: HF100H+  OR: HF1202H PowerPlus 	HF1202H PowerPlus 
Digital X-ray Panel Supplied	Toshiba FDX3543RP	Toshiba FDX3543RPW. Note: this panel was cleared in K143257	PerkinElmer XRpad 4336 (Cleared in K140551)	PerkinElmer XRpad 4336 (Cleared in K140551)

Characteristic	Predicate: CMDR-2ST & CMDR-2SLWT Digital X-Ray System K141885	CMDR 2ST (Multiple Models)	CMDR 2SPE (Multiple Models)	Integris
Panel Performance	Pixel size 143 x 143µm Matrix size 2448×2984 Size 14” x 17”	Pixel Pitch 140 µ m Pixel Matrix 2466 (H) x 3040 (V) Size 14” x 17”	Pixel size 100 x 100µm Matrix size 3556 × 4320 Size 14” x 17” (Cleared in K140551)	Pixel size 100 x 100µm Matrix size 3556 × 4320 Size 14” x 17” (Cleared in K140551)
Panel Power Source	DC Adapter	DC Adapter or Lithium Ion rechargeable battery	DC Adapter or Lithium Ion rechargeable battery	DC Adapter or Lithium Ion rechargeable battery
Panel Interface	Ethernet	Ethernet or Wi-Fi wireless, panel cleared in	Ethernet or Wi-Fi wireless, panel cleared in K140551	Ethernet or Wi-Fi wireless, panel cleared in K140551
Performance Standard	21 CFR 1020.30	SAME	SAME	SAME
PACS software	dicomPACS® (Cleared in K141440)	dicomPACS® (Cleared with the Toshiba panels in K141440)	dicomPACS® (Cleared with the PerkinElmer panel in K141440)	dicomPACS® (Cleared with the PerkinElmer panel in K141440)
Power Source	120 V 50/60 Hz AC 20 amp	SAME	SAME	SAME
Digital Panel Power Source	120 V 50/60 Hz AC	120 V 50/60 Hz AC or Lithium Ion Rechargeable Battery.	120 V 50/60 Hz AC or Lithium Ion Rechargeable Battery.	120 V 50/60 Hz AC or Lithium Ion Rechargeable Battery.
Digital Panel				

Characteristic	Predicate: CMDR-2ST & CMDR-2SLWT Digital X-Ray System K141885	CMDR 2ST (Multiple Models)	CMDR 2SPE (Multiple Models)	Integris
Model Details	HF120/60HPPWV Generator with Toshiba FDX3543RP and O&R Imaging Software	CMDR 2ST 100+/ DP for Dell Precision or a /DL for Dell Latitude Computer Uses HF100H+ Generator with Toshiba FDX3543RP and O&R Imaging Software CMDR 2STW 100H+/DP for Dell Precision or a /DL for Dell Latitude Computer Uses HF100H+ Generator with Toshiba FDX3543RPW and O&R Imaging Software CMDR 2STW 1202/DP for Dell Precision or a /DL for Dell Latitude Computer Uses HF1202 Generator with Toshiba FDX3543RPW and O&R Imaging Software CMDR 2STW-MIL (Uses Dell Latitude 14 with the HF120/60HPPWV Generator with Toshiba FDX3543RPW and O&R Imaging Software	CMDR 2SPE 120/60 PP CMDR 2SPE 100H+ CMDR 2SPE 1202 (The suffix is the generator model number) Add a /DP for Dell Precision Computer or a /DL for Dell Latitude Computer All use the PerkinElmer XRpad 4336 and O&R Imaging Software	Integris. Panel: Perkin Elmer Wireless XRpad 4336 and O&R Imaging Software Computer: Beckhoff C6920/C6925 Generator: HF1202H PowerPlus

7) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device. The results of bench testing indicates that the new devices are 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. NO HARDWARE OR SOFTWARE MODIFICATIONS TO ALREADY CLEARED DEVICES WERE REQUIRED TO CREATE THESE NEW MODELS.

8) **Summary of non-clinical testing:** Prototype systems covering **all** generator/panel combinations were assembled and tested. First the dicomPACS® software was installed on the Dell Inspiron laptop computer. The proper installation was verified by running the software. A Wi-Fi connection was confirmed between the PerkinElmer panel and the Dell laptop. The panel was confirmed to be charged and turned on. Then the MinXray HF portable generator was turned on. The MinXray portable X-ray generator was set to generate an exposure. The generator was aimed at the PerkinElmer 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, and has undergone testing for compliance with UL 60601-1 (2005) (Electrical medical device safety), IEC 60601-1-2 (2007) (Electromagnetic Compatibility). Additionally, the HF1202H PowerPlus generator meets IEC 60601-2-54: Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. The other generators were designed and cleared prior to the issuance of this standard. The software supplier Oehm Und Rehbein GmbH verified compatibility with the new PerkinElmer digital panel and supplied us with a test report. The risks and hazardous impacts of the device modification were analyzed by FMEA methodology. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented as part of product design. The overall assessment concluded that all identified risks and hazardous conditions were successfully mitigated and accepted.
We employed the i.b.a. Test Device DIGI-13, a device for quality tests at CR and DR systems (e.g. for acceptance tests according to DIN V 6868-58 and constancy tests according to DIN 6868-13) to obtain images from both the predicate and the new digital panel. All panel/generator combinations were tested. The images were evaluated and found to be of diagnostic quality.

9) **Summary of clinical testing:** Clinical testing was not required to establish substantial equivalence.

10) **Conclusion: After analyzing bench and clinical tests, it is the conclusion of MinXray Inc. that the modified Digital Diagnostic X-Ray Systems are 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.**