DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 1, 2016

PerkinElmer, Inc.
% Ms. Dawn M. Spooner
Associate Director, Regulatory Affairs
940 Winter Street
WALTHAM MA 02451

Re: K161942
Trade/Device Name: XRpad2 3025 HWC-M Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 14, 2016
Received: July 15, 2016

Dear Ms. Spooner:

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

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)*

K161942

Device Name

XRpad2 3025 HWC-M Flat Panel Detector

Indications for Use *(Describe)*

The XRpad2 3025 HWC-M, when used with a radiographic imaging system, is indicated for use in generating radiographic images of human anatomy for diagnostic X-ray procedures, wherever conventional screen-film (SF), digital radiography (DR), or computed radiography (CR) systems may be used. It is not intended 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
XRpad2 3025 HWC-M Flat Panel Detector

This summary of 510(k) safety and effectiveness information is supplied in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K161942

August 15, 2016

Submitted By:

PerkinElmer Medical Imaging
2175 Mission College Blvd.
Santa Clara, CA 95054
U.S.A.

Contact Person:

Dawn Spooner
Associate Director, Regulatory Affairs
Tel. 781-663-6071
Fax. 781-663-5969

Device Name: **PerkinElmer XRpad2 3025 HWC-M Flat Panel Detector**

Classification:

Product Code:	MQB
Classification Name:	Stationary X-ray System
Classification Regulation:	21 CFR 892.1680

Predicate Device: **PerkinElmer XRpad 4336 MED Flat Panel Detector**

510(k) Clearance:	K140551; August 1, 2014
Product Code:	MQB
Classification Name:	Stationary X-ray System
Classification Regulation:	21 CFR 892.1680

Device Description:

The XRpad2 3025 HWC-M is a lightweight, cassette-sized, flat panel X-ray detector for digital radiography. The X-ray detector consists of an amorphous silicon flat panel with a directly deposited CsI:Tl scintillator and dedicated read-out, scan, and control electronics, all packaged in a carbon-fiber and aluminum enclosure. The outside dimensions of the detector are 332.0 mm × 282.0 mm × 15.5 mm, which fits into a standard X-ray cassette Bucky.

The detector can be integrated into a fixed room X-ray system to enable digital radiography. The following accessories are available for the XRpad2 3025 HWC-M:

- XRpad LBC-2 (Lithium Battery Charger)
- XRpad IPU-2 (Interface and Power Unit)
- XRpad LPT2 Detector Cable
- XRpad Protective Insert 3025
- AC Cable IEC 60320 C13 DE
- AC Cable IEC 60320 C13 US
- Trigger Cable 5 m/16.5 ft.
- Trigger Cable 20 m/65.5 ft.
- GigE Interface Cable 7.6 m/25 ft.
- GigE Interface Cable 15.25 m/50 ft.
- GigE Interface Cable 30.5 m/100 ft.

Indications For Use:

The XRpad2 3025 HWC-M, when used with a radiographic imaging system, is indicated for use in generating radiographic images of human anatomy for diagnostic X-ray procedures, wherever conventional screen-film (SF), digital radiography (DR), or computed radiography (CR) systems may be used. It is not intended for mammographic use.

Comparison Chart

Characteristics	Model PerkinElmer XRpad 4336 MED (K140551)	Proposed Model PerkinElmer XRpad2 3025 HWC-M
Intended Use / Indications for Use	The XRpad 4336 MED when used with a radiographic imaging system, is indicated for use in generating radiographic images of human anatomy for diagnostic X-ray procedures, wherever conventional screen-film (SF), digital radiography (DR), or computed radiography (CR) systems may be used. It is not intended for mammographic use.	Same
Panel	Single substrate amorphous silicon active TFT/diode array	Same
Scintillator	Direct deposition CsI:Tl	Same
Pixel pitch	100 µm	Same
Pixel matrix	3556 × 4320 pixels	2508 × 3004
Limiting resolution	5 lp/mm	Same
Binning capable	2 × 2 binning for 200 µm	Same
Data transmit area	355 mm × 432 mm	250 mm × 300 mm
External dimensions (w × l × h)	384 mm × 460 mm × 15 mm	282 mm × 332 mm × 15.5 mm
Weight	3.8 kg	1.8 kg
Housing material	Aluminum with carbon-fiber	Same
Finish	Matte carbon-fiber front with white silk-screen active area markers	Same
Communication interface	Gb Ethernet or 802.11n WiFi	Same
WiFi band	5.1-5.3 GHz	5.1-5.9 GHz
X-ray synchronization interface	Dedicated trigger in/out signal lines or Automatic Exposure Detection	Same
Power	External power supply or battery	Same
Software library	Windows OS	Windows and Linux OS

Summary of Studies:

The proposed new device and the XRpad predicate device utilize similar technology and materials, are similar in design and construction, and have the same intended use. The construction and physical characteristics of the PerkinElmer XRpad2 3025 HWC-M compared to the predicate PerkinElmer XRpad 4336 MED are similar. The difference is related to the decrease in dimensions and does not impact image quality.

The PerkinElmer XRpad2 3025 HWC-M flat panel detector has successfully completed internal non-clinical testing, complies with standards and regulations such as UL and IEC. A new clinical study was not required for the XRpad2 3025 HWC-M device. The predicate device, XRpad 4336 MED, was cleared using clinical data derived from testing to support K122495 (XRD 1622 AP3 MED) and applicable to the predicate device. The XRpad2 3025 HWC-M device differences do not invalidate the applicability of the clinical study data submitted in K122495. Through non-clinical testing, we have demonstrated the clinical data collected with the (XRD 1622 AP3 MED) in K122495 is also applicable to the XRpad2 3025 HWC-M device as it was applicable for the XRpad 4336 MED device.

Summary of Design Control and Risk Management:

The XRpad2 3025 HWC-M flat panel X-ray detector is a modification of the XRpad 4336 MED (K140551). The modifications are related to the decrease in dimensions and do not impact image quality.

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.

Summary of Non-Clinical Data:

To demonstrate the equivalence of the PerkinElmer XRpad2 3025 HWC-M to the predicate device, PerkinElmer has performed internal non-clinical testing and demonstrated compliance with accepted standards and regulations such as UL and IEC following the non-clinical considerations outlined in the Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, August, 1999. The non-clinical testing was conducted and demonstrated the main physical values of the XRpad2 3025 HWC-M such as DQE and MTF are comparable to the predicate device. The non-clinical performance testing conducted and resulting data demonstrate substantial equivalence.

Substantial Equivalency:

The proposed device and predicate device (XRpad 4336 MED flat panel detector) both utilize similar technology and materials, are similar in design and construction, and have been shown to produce images of equivalent diagnostic quality. Both devices are intended for use in generating radiographic images of human anatomy for diagnostic X-ray procedures, wherever conventional screen-film (SF), digital radiography (DR), or computed radiography (CR) systems may be used. The devices are not intended for mammographic use. Both devices produce digital images which can be transmitted to imaging software of the X-ray unit.

Conclusion:

Similar to the predicate device, the XRpad2 3025 HWC-M has comparable performance and operational standards. Potential hazards have been studied and controlled by a Risk Management Plan. The non-clinical software verification and validation test results demonstrate that the PerkinElmer XRpad2 3025 HWC-M complies with international and FDA recognized consensus standards and meets the acceptance criteria and is adequate for its intended use.

Based on the information supplied in this 510(k) PerkinElmer concludes, the XRpad2 3025 HWC-M is substantially equivalent to the currently marketed device, XRpad 4336 MED (Kl40551) in terms of safety and effectiveness.