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

August 1, 2014

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

Re: K140551
Trade/Device Name: 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
Dated: May 05, 2014
Received: May 06, 2014

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

Janine M. Morris
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)*

K140551

Device Name

XRpad 4336 MED

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary

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 K140551

August 1, 2014

Submitted by: PerkinElmer Medical Imaging
2175 Mission College Blvd.
Santa Clara, CA 95054

Contact Person:
Primary: Dawn Spooner
Tel. 781-663-6071
Fax. 781-663-5969

Trade Name: PerkinElmer XRpad 4336 MED Flat Panel Detector

Common Name: Stationary X-ray system (21 CFR 892.1680)
Regulation:

Classification Name: Stationary X-ray system

Classification: 90 Radiology

Product Code: (MQB)

Predicate device: XRD 1622 AP3 MED X-ray system (Flat Panel Detector in system) [K122495]

Device Description:

The XRpad 4336 MED is a flat panel X-ray detector consisting of an amorphous silicon panel with a directly deposited CsI:Tl scintillator.

The XRpad 4336 MED detector has an active area of 43.2cm x 35.5cm at a pixel pitch of 100µm. Data and control communication is accomplished via a Gigabit Ethernet interface or 802.11n WiFi.

The detector can be integrated into a fixed room X-ray system to enable digital radiography. The following accessories are available for the XRpad 4336 MED

- XRpad™ LBP (Lithium Battery Pack)
- XRpad™ LBC (Lithium Battery Charger)
- XRpad™ IPU (Interface Power Unit)
- XRpad™ LPT Detector Cable, 3m/100ft
- XRpad™ Protective Insert
- XRpad™ 4336 Connector Cover Set
- Trigger cable (in lengths of 5 m or 20 m)
- GigE interface cable (in lengths of 7.6 m, 15.25 m, or 30.5 m)

The XRpad 4336 MED detector is designed to work with any X-ray system (consisting of an X-ray source, generator, collimator, and positioner) intended for use in generating radiographic images of human anatomy for diagnostic X-ray procedures. Applicable detector parameters, such as dynamic range, exposure time range, energy range, image size, resolution, detective quantum efficiency, etc are designed to support the necessary compatibility.

Intended 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.

Comparison Chart:

Comparison of the XRpad 4336 MED device with its predicate.

Characteristics	Proposed device PerkinElmer XRpad 4336 MED	Predicate device (K122495) PerkinElmer XRD 1622 AP3 MED
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 matrix	3556 × 4320 pixels	2048 × 2048 pixels
Pixel pitch	100 μm	200 μm
Active area	355 mm × 432 mm	409 mm × 409 mm
External dimensions (w × l × h)	384 mm × 460 mm × 15 mm	500 mm × 560 mm × 22 mm
Weight	Approximately 4 kg	Approximately 9 kg
Housing material	Aluminum with carbon-fiber	Aluminum
Communication interface	Gb Ethernet or 802.11n WiFi	Gb Ethernet
Power	External power supply or battery	External power supply

Summary of Studies:

The PerkinElmer XRpad 4336 MED flat panel detector has successfully completed internal nonclinical testing, complies with standards and regulations such as UL and IEC. No clinical studies were conducted in support of the XRpad 4336 MED as agreed upon during PreSubmission discussions with the Agency for the predicate device (K122495). The conduct of a clinical concurrence study was deemed unnecessary to demonstrate substantial equivalence.

Substantial Equivalency:

The proposed device and predicate device (XRD 1622 AP3 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:

The PerkinElmer XRpad 4336 MED is substantially equivalent to the PerkinElmer XRD 1622 AP3 MED (K122495) flat panel detector predicate device.