July 3, 2018

Varex Imaging Corporation
% Mr. Paul Sawicki
Director, Quality Assurance and Regulatory Affairs
2175 Mission College Blvd.
SANTA CLARA CA 95054

Re: K181526
Trade/Device Name: XRpad2 4343 HWC-M
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 7, 2018
Received: June 11, 2018

Dear Mr. Sawicki:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181526

Device Name

XRpad2 4343 HWC-M

Indications for Use *(Describe)*

The XRpad2 4343 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

XRpad2 4343 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: K181526

Date: June 27, 2018

Submitted By: Varex Imaging Corporation
2175 Mission College Blvd.
Santa Clara, CA 95054
U.S.A.

Contact Person: Paul Sawicki
Director, Quality Assurance and Regulatory Affairs
Tel. 408-469-6462
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E-mail: paul.sawicki@vareximaging.com

Device Name: **XRpad2 4343 HWC-M Flat Panel Detector**

Classification: Product Code: MQB
Classification Name: Solid state X-ray imager (flat panel/digital imager)
Regulation Name: Stationary X-ray system
Classification Regulation: 21 CFR 892.1680

Predicate Device: **XRpad 4336 HWC-M Flat Panel Detector**
510(k) Clearance: K161966; September 8, 2016
Product Code: MQB
Classification Name: Solid state X-ray imager (flat panel/digital imager)
Regulation Name: Stationary X-ray system
Classification Regulation: 21 CFR 892.1680

Device Description:

The XRpad2 4343 HWC-M is a wireless, lightweight, cassette-sized, flat panel X-ray detector for digital radiography. It fits into a conventional table or wall-stand Bucky, just like a film-screen cassette. 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 460 mm × 460 mm × 15.5 mm, which fits into a standard X-ray cassette Bucky.

The detector can be integrated with an X-ray system to enable digital radiography. The following accessories are available for the XRpad2 4343 HWC-M:

- XRpad LBC-2 (Lithium Battery Charger)
- XRpad IPU-2 (Interface and Power Unit)
- XRpad LPT2 Detector Cable
- XRpad Protective Insert
- 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.

Device Software:

The XRpad2 4343 HWC-M device, like the predicate, relies on the X-ray Imaging Software Library (XISL), to control the detector from the host computer. The XISL is a C/C++-coded software library that provides parameterized functions to interface the device to a host work station via an IP Network connection. By use of the application programming interface (API) of XISL one can acquire images and configure all use functions of the XRpad2 4343 HWC-M detector.

Indications for Use:

The XRpad2 4343 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 XRpad2 4336 HWC-M (K161966)	Proposed Model XRpad2 4343 HWC-M
Intended Use / Indications for Use	The XRpad 4336 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.	Same
Panel	Single substrate amorphous silicon active TFT/diode array	Same
Scintillator	Direct deposition CsI:Tl	Same
Pixel pitch	100 µm	Same
Pixel matrix	3524 × 4288	4288 × 4288
Limiting resolution	5 lp/mm	Same
Binning capable	2 × 2 binning for 200 µm	Same
Data transmit area	352 mm × 429 mm	429 mm × 429 mm
External dimensions (w × l × h)	384 mm × 460 mm × 15.5 mm	460 mm × 460 mm × 15.5 mm
Weight	3.2 kg	3.8 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	5.15 - 5.85 GHz	Same
X-ray synchronization interface	Dedicated trigger in/out signal lines or Automatic Exposure Detection	Same
Power	External power supply or battery	Same
Software library	X-ray Imaging Software Library (XISL), which provides control of detector configuration and image acquisitions from a host computer	Same
Software operating system	Windows and Linux OS	Same

Summary of Studies:

The proposed new device (XRpad2 4343 HWC-M) and the predicate device (XRpad2 4336 HWC-M) utilize similar technology and materials, are similar in design and construction, and have the same intended use. The construction and physical characteristics of the two devices are similar. The difference is related to a 76 mm increase in the width dimension of the proposed device, which does not impact image quality.

The XRpad2 4343 HWC-M flat panel detector has successfully completed internal non-clinical testing, and complies with IEC and ISO standards and regulations related to medical safety, EMC, and bio-compatibility. A clinical study was not required for the XRpad2 4343 HWC-M device. Taking into consideration the similarities in construction and physical characteristics of the XRpad2 4343 HWC-M to the predicate device, substantial equivalence of imaging performance between the two XRpad2 flat panel detectors can be demonstrated by a comparison of the non-clinical testing results only.

Summary of Design Control and Risk Management:

The XRpad2 4343 HWC-M flat panel X-ray detector is a modification of the XRpad2 4336 HWC-M (K161966). The modifications are related to an increase in the width dimension of the device, 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 XRpad2 4343 HWC-M to the predicate device, Varex Imaging has performed internal non-clinical testing and demonstrated compliance with accepted IEC and ISO standards and regulations. In addition, Varex Imaging has followed the non-clinical considerations outlined in the Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices, September, 2016. This testing demonstrated that critical image quality performance attributes, such as MTF and DQE, of the XRpad2 4343 HWC-M are comparable to the predicate device. The resulting data from the conducted non-clinical tests demonstrate substantial equivalence.

Substantial Equivalency:

The proposed device and predicate device (XRpad2 4336 HWC-M 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 4343 HWC-M has comparable performance and comply with similar operational standards. Potential hazards have been studied and controlled by a Risk Management Plan. The non-clinical verification and validation test results demonstrate that the XRpad2 4343 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) Varex Imaging concludes, the XRpad2 4343 HWC-M is substantially equivalent to the currently marketed device, XRpad2 4336 HWC-M (K161966) in terms of safety and effectiveness.