NOV 2 8 2012

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 K122495

807.92(a)(1):

Date: November 17, 2012

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

Contact Person:
Primary: Kay A. Taylor
Tele: 317 418-1735
Fax: 317 536-3064

807.92(a)(2):

Trade Name: PerkinElmer XRD 1622 AP3 MED Flat Panel Detector

Common Name: Flat Panel Digital Detector (21 CFR 892.1650)
Regulation:

Classification Name: Solid State X-ray Imager

Classification: 90 Radiology

Product Code: (MQB)

807.92(a)(3):

Predicate device: Definium 5000 X-ray system (Flat Panel Detector in system) [K063283]

807.92(a)(4):

Device Description:

The XRD 1622 AP3 MED is a flat panel x-ray detector consisting of an amorphous silicon panel with a directly deposited CsI:Tl scintillator.

The XRD 1622 AP3 MED detector has an active area of 41cm x 41cm at a pixel pitch of 200µm. Data and control communication is accomplished via a Gigabit Ethernet interface.

The detector can be integrated into a fixed room x-ray system to enable digital radiography. The following accessories are available for the XRD 1622AP3 MED

- Power supply XRD-LPM (for indoor usage only)
- Power supply XRD-EPS (for indoor or outdoor usage)
- DC cable for XRD-EPS (in lengths of 7.6 m, 15.3 m or 30.5 m)
- AC cable for XRD EPS (country specific AC connector)
- Trigger cable (in lengths of 5 m or 20 m)
- GigE interface cable (in lengths of 7.6 m, 15.3 m, 30.5 m, or 61m)

807.92(a)(5):

Intended Use:

The XRD 1622 AP3 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.

807.92(a)(6):

Technological Characteristics Comparison:

Comparison of the XRD 1622 AP3 MED device with its predicate.

PerkinElmer XRD 1622 AP3 MED		
Characteristics	**Proposed Device**	**Predicate (K063283)**
Intended Use/Indications for Use	The XRD 1622 AP3 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.	The Definium 5000 x-ray system is intended for use by a qualified / trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposres of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Note: The predicate submission (K063283) was to combine two previously cleared devices; the Sedecal X Plus LS Plus Universal Radiographic System and the GE Medical Systems Digital Radiographic Detector (K042876) to which substantial eqivalency is claimed for the XRD 1622 AP3 MED.

Panel	Single substrate a-Si TFT/diode array	Same
Scintillator	Direct deposit CsI:Tl	Same
Active area	40.96cm x 40.96cm	Same
Pixel pitch	200μm	Same
Power	External power supply	Same
Communication	Ethernet	Same

807.92(b)(1):

Summary of Non-Clinical Studies:

The PerkinElmer XRD 1622 AP3 MED flat panel detector has successfully completed internal nonclinical testing, complies with standards and regulations such as UL and IEC. The device has completed verification and validation testing to confirm it meets the specifications and operates as planned. Tests included image quality test with internal experts. The product, manufacturing and development processes have been showen to conform to product safety, radiology and imaging standards.

807.92(b)(2):

Summary of Clinical Studies:

The PerkinElmer XRD 1622 AP3 MED flat panel detector has successfully completed external testing in actual user testing facility and was found to produce images of equivalent diagnostic quality in a study of 30 image pairs of different anatomical regions reviewed by three board certified radiologists.

807.92(b)(3):

Substantial Equivalency:

The proposed device and predicate device (flat panel detector of the predicate) both utilize similar technology and materials, are similar in design and construction, and have been shown to produce images of equivalent diagnostic quality in a clinical setting. 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 XRD 1622 AP3 MED is substantially equivalent to the flat panel detector of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 28, 2012

PerkinElmer
C/O Ms. Kay A. Taylor, MT (ASCP) RAC
Vice President, Quality and Clinical Affairs
8275 Carloway Road
INDIANAPLOIS IN 46236

Re: K122495
Trade/Device Name: PerkinElmer XRD 1622 AP3 MED Flat Panel Detector
Regulation Number: 21 CFR 892.1650
Regulation Name: Image0intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 17, 2012
Received: November 20, 2012

Dear Ms. Taylor:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Michael D. O'Hara

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K122495

Device Name: **PerkinElmer XRD 1622 AP3 MED Flat Panel Detector**

Indications for Use:

The XRD 1622 AP3 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.

Prescription Use XXXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device (ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K122495