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

June 23, 2015

KUB Technologies, Inc.
% Vikram Butani
President
270 Rowe Avenue, Unit E
MILFORD CT 06461

Re: K151221
Trade/Device Name: Kubtec DIGIVIEW 395
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 5, 2015
Received: May 7, 2015

Dear Vikram Butani:

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.
Acting 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)*

K151221

Device Name
Kubtec DIGIVIEW 395

Indications for Use *(Describe)*

The DIGIVIEW 395, 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.

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."

DIGIVIEW 395
510(K) Summary

Identification of Device:

Proprietary/Trade Name:	DIGIVIEW 395 (DV395)
Classification name:	SYSTEM, STATIONARY X-RAY
Classification:	Class II
CFR Section:	21 CFR 892.1680
Product Codes:	MQB
Common Name:	Stationary X-ray system

Predicate Device:

Device Name:	Perkinelmer, XRpad 4336 MED Flat Panel Detector
510(k) Number:	K140551
Classification	Class: II
Regulation Number:	21 CFR 892.1680
Product Code:	MQB
Regulation Name:	Stationary x-ray system

I. INDICATIONS FOR USE

The DIGIVIEW 395, 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.

II. DEVICE DESCRIPTION

The DIGIVIEW 395 is a flat panel X-ray detector consisting of an amorphous silicon panel with a directly deposited CsI:TI scintillator.

The DIGIVIEW 395 detector has an active area of 43.2 cm x 35.5 cm 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 DIGIVIEW 395

- DV395 LBP (Lithium Battery Pack)
- DV395 LBC (Lithium Battery Charger)
- DV395 IPU (Interface Power Unit)
- DV395 LPT Detector Cable, 3m/100ft
- DV395 Protective Insert

- DV395 Connector Cover Set
- Trigger cable (5m or 20m)
- GigE interface cable (7.6m, 15.25m, or 30.5m)

The DIGIVIEW 395 is designed to work with X-ray systems (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 that the following parameters may fulfil. 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.

Energy range for compatibility is 20-150kVp.

The DIGIVIEW 395's auto exposure detection (AED) mode allows integration with OEM systems that there is no access to intercept the Prep/Expose signal.

Any modifications for hard wire integration to a previously installed OEM x-ray system that was utilized for analog or Computed Radiography are limited to integration between the hand-switch and it's connector to the x-ray console.

All integration work must be conducted by qualified service personnel and proper operation verified before releasing system for use on patients.

III. SUMMARY OF STUDIES AND SAFETY

Kubtec's DIGIVIEW 395 successfully completed internal safety testing requirements to recognized consensus standards listed below. No clinical studies were conducted in support of the DIGIVIEW 395 as agreed upon during Pre-Submission discussions with the Agency for the predicate device (K140551). The conduct of a clinical concurrence study was deemed unnecessary to demonstrate substantial equivalence.

Recognized Consensus Standards

- IEC 62220-1 Edition 1.0 (2003-10) Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
- IEC 62220-1-3 Edition 1.0 (2008-06) Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging
- IEC 62494-1 Edition 1.0 (2008-08) Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography
- IEC PAS 61910-1 First Edition 2007-07 Medical electrical equipment - Radiation dose documentation - Part 1: Equipment for radiography and radioscopy
- NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set

- IEC 60601-2-43 - Ed. 2.0 2010-03 Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures
- NEMA XR 24-2008 (R2014) Primary user controls for interventional angiography x-ray equipment

IV. BASIS FOR THE SUBMISSION

This summary of 510(k) safety and effectiveness information is supplied in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 to show Substantial Equivalence of the proposed device and the predicate device.

- PerkinElmer XRpad 4336 MED (K140551)

There is no change for the indication for use from the predicate 510(k) approved device.

Design and Use of the Device		
Question	**YES**	**NO**
Is the device intended for prescription use (21 CFR 801 Subpart D) ?	X	
Is the device intended for over-the-counter use (21 CFR807 Subpart C)?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

V. COMPARISON CHART

Characteristics	**Proposed device Kubtec DIGIVIEW 395**	**Predicate device (K140551) PerkinElmer XRpad 4336 MED**

Intended Use/ Indications for Use	The DIGIVIEW 395, 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 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.
Panel	Single substrate amorphous silicon active TFT/diode array	Same
Scintillator	Direct deposition Csi:TI	Same
Pixel matrix	3556 x 4320 pixels	Same
Pixel Pitch	100 µm	Same
Active area	355 mm x 432 mm	Same
External dimensions (w x l x h)	384 mm x 460 mm x 15 mm	Same
Weight	Approximately 4 kg	Same
Housing material	Aluminum with carbon-fiber	Same
Communication interface	Gb Ethernet or 802.11n WiFi	Same
Power	External power supply or battery	Same

VI. SUBSTANTIAL EQUIVALENCE

The proposed device and predicate device DIGIVIEW 395 is substantially equivalent to the following currently cleared predicate device:

a. PerkinElmer XRpad 4336 MED (K140551)

The proposed and predicate devices utilize the same technology and materials, comparable safety and effectiveness features, and is similar in design and construction. The Indications for Use and labeling are the same and our labeling contain the required Cautions, Warnings and Contraindications consistent to those required for similar cleared devices. Both systems produce digital images which can be sent to hardcopy printers, softcopy diagnostic workstations and/or stored in archive. The only difference is utilization of Kubtec's DIGICOM

software to manage operation of detector which had previously received 510(K) with the Kubtec KUB250 (K141539) and the Kubtec Digiview 250 (K103348)

VII. CONCLUSION

The DIGIVIEW 395 is as safe and effective as the predicate device, has no technological differences in the hardware, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices and conforms to applicable medical device safety standards. The only difference is utilization of Kubtec's DIGICOM software to manage operation of detector which had previously received 510(K) with the Kubtec KUB250 (K141539) and the Kubtec Digiview 250 (K103348)