K103348

OCT 2 0 2011

510(k) Summary

Prepared: August 2, 2011

Submitter:

Company Name: KUB Technologies, Inc.

Company Address: 270 Rowe Avenue, Unit E

Milford, CT 06460

Contact Person: Mr. Vikram Butani

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Proposed Device:

Reason For 510(k): New Model

Trade Name: Kubtec

Model Name: Digiview 250 ®

Classification Name: MQB, Solid State X-ray Imager

FDA 510(k) #: K103348

Predicate Device:

Trade Name: Canon

Model Name: CXDI-60G

Classification Name: MQB, Solid State X-ray Imager

FDA 510(k) #: K081648

Description Of Device:

The Kubtec Digital Radiography DIGIVIEW 250 ® is a CMOS based solid state x-ray imager which has a 192 x 246 mm imaging area. The Digital Radiography DIGIVIEW 250® imager intercepts X-ray photons after they pass through anatomy and surrounding air and converts the X-ray photons into electrical signals. These resultant electric signals are converted into digital values which are transmitted for remote viewing. The DIGIVIEW 250 ® system features a DICOM 3.0 compliant software, DIGICOM. The DIGICOM software enables the display and analysis of x-ray images; either live (real

time) or previously captured and the storage and transmission of these images to PACS systems.

Intended Use:

The DIGIVIEW 250 is indicated for use in generating radiographic images of human anatomy. The device is intended to provide digital x-ray image capture for conventional film/screen radiographic examinations and replace radiographic film/screen systems in all general purpose diagnostic procedures. The device is not intended for mammography applications.

Comparison Table:

Kubtec DIGIVIEW 250 ® (Proposed) To Canon CXDI-60G (Predicate):

Characteristic:	Proposed Device	Predicate Device
Model:	Kubtec DIGIVIEW 250 ®	Canon CXDI-60G
Energy Source:	100-240 V Power Box(6.6 VAC out)	100-240V "Power Box"
Digital Resolution	2000 x 2560 pixels (5.12 million) 5.2 lp/mm	1464 x 1776 pixels (2.6 million) 3.1 lp/mm
Pixel Pitch;	96 microns	160 microns
Bit depth:	14 bit	14 bit
DICOM:	Dicom compatible	Dicom compatible
Image readout:	750 milliseconds	approx. 3 seconds
Interface:	Ethernet	Ethernet
Scintillator:	GdOS, gadolinium oxysulfide	GdOS, gadolinium oxysulfide
Dynamic range:	78 dB	80 dB
Operating temperature:	0 -50 Degrees C	5 -35 Degrees C
Humidity:	0 - 80% R.H.	30 -75% R.H.
Method of Control:	Software Driven	Software Driven
Performance Standard:	21 CFR 1020.30	21 CFR 1020.30
Classification name:	Solid State X-ray imager	Solid State X-ray imager
Detector Type:	CMOS	Amorphous Silicon
Housing:	Molded plastic with rounded corners and built-in handle	Molded plastic with rounded corners and built-in handle

Comparison:

The imaging area of the Kubtec DIGIVIEW 250 ® is 192 x 246 mm as compared to the 230 x 280mm area of the Canon CXDI-60G.

The Kubtec DIGIVIEW 250 ® has a housing measuring 355 x 285 x 24 mm compared to the Canon CXDI-60G housing at 344 x 380 x 22.5 mm and has a comparable shape with integral handle molded into the case.

Both the proposed and predicate device utilize GdOS (gadolinium oxysulfide) scintillators for the fluorescing screen.

The Kubtec DIGIVIEW 250 ® utilizes CMOS as its detector. Canon CXDI-60G uses amorphous silicon detectors. CMOS (complementary metal-oxide semiconductor) technology offers higher sensitivity and signal to noise performance with faster speed and better resolution.

The image readout time on the Kubtec DIGIVIEW 250 ® is 750 milliseconds as compared to the Canon CXDI-60G time of 3 seconds.

The resolution of the Kubtec DIGIVIEW 250 ® is 2,000 x 2,560 pixels (5.12 million) as compared to the predicate Canon CXDI60G of 1464 x 1776 pixels (2.6 million).

The pixel pitch of the Kubtec DIGIVIEW 250 ® is 96 microns compared to 160 microns on the Canon predicate device. The bit depth on both devices is 14 bits.

Both the proposed device, Kubtec DIGIVIEW 250 ® and the predicate device, Canon CXDI 60G are DICOM compatible, software driven, and utilize an Ethernet interface.

Conclusion:

The performance data, non-clinical testing, and design process demonstrate that the Kubtec DIGIVIEW 250 ® is as safe and effective as the Canon CXDI-60G, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

Based on the information submitted, similarity to the predicate device (Canon Digital Radiography CXDI-60G), and the results of our design control activities and non-clinical testing, it is the opinion of Kubtec that the Kubtec Digital Radiography DIGIVIEW 250 ® described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Vikram Butani
President
KUB Technologies
270 Rowe Avenue, Unit E
MILFORD CT 06460

AUG 23 2013

Re: K103348
Trade/Device Name: Kubtec DIGIVIEW 250
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 30, 2011
Received: October 3, 2011

Dear Mr. Butani:

This letter corrects our substantially equivalent letter of October 20, 2011.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

kubtec
GOING BEYOND THE SURFACE

Indications for Use

510(k) Number (if known): K103348

Device Name: Kubtec DIGIVIEW 250

Indications For Use:

The Digiview 250 is indicated for use in generating radiographic images of human anatomy. The device is intended to provide digital x-ray image capture for conventional film/screen radiographic examinations and replace radiographic film/screen systems in all general purpose diagnostic procedures. The device is not intended for mammography applications.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, The Office of In Vitro Diagnostics

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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