U.S. FOOD & DRUG ADMINISTRATION

KUB Technologies, Inc.
% Chester Lowe
Chief Technology Officer
111 Research Drive
STRATFORD CT 06615

June 20, 2019

Re: K183624
Trade/Device Name: Kubtec Mozart (Xpert42)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MWP
Dated: May 14, 2019
Received: May 20, 2019

Dear Mr. Lowe:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia Mills, Ph.D,
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K183624

Device Name
Kubtec MOZART (XPERT42)

Indications for Use *(Describe)*
The MOZART(XPERT42) is a Cabinet x-ray system that is used to provide two dimensional and three dimensional tomographic digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

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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MOZART (XPERT42)
Stationary X-ray System

510(k) Summary
KUB Technologies, Inc.

510(k) K183624

510(K) Summary

Date Prepared: May 14, 2019

Submitter's Information

Applicant:

KUB Technologies, Inc.
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Stratford, CT 06615 USA

Contact Person:

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Establishment Number: KUB Technologies, Inc. # 3006051164

Identification of Device:

Proprietary/Trade Name:	Kubtec MOZART (XPERT 42)
Classification name:	Cabinet X-ray System
Classification:	Class II
CFR Section:	21 CFR 892.1680
Product Codes:	MWP
Common Name:	Stationary X-ray System

Predicate Device:

Device Name:	Kubtec XPERT 40
510(k) Number:	K071233
Classification	Class: II
Regulation Number:	21 CFR 892.1680

Product Code: MWP
Regulation Name: Stationary X-ray System

I. INDICATIONS FOR USE

The MOZART(XPERT42) is a Cabinet x-ray system that is used to provide two dimensional and three dimensional tomographic digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

II. DEVICE DESCRIPTION

The MOZART Specimen Radiography System is a Cabinet X-ray System specifically designed to provide high detail radiographic imaging of surgically excised medical specimens both in two-dimensional and three-dimensional tomosynthesis views.

- It is the only cabinet specimen imaging system to utilize 3-D Tomosynthesis technology.
- Creates images in 1mm digital slices of the specimen, allowing physicians to evaluate the specimen layer by layer.

It has been clinically proven for the following:

- Provides more anatomical information than single planar 2-D imaging alone.
- More precisely identifies the locations and extent of lesions than single planar 2-D imaging alone.
- Excludes overlying skin and surrounding breast tissue.
- Identifies surgical margins in three axes.
- Facilitates lower re-excisions by visualizing more information than 2-D Imaging

Tomosynthesis is an advanced radiographic application that produces individual coronal “slice” images through an anatomical region of inters (ROI). To produce these slices multiple projection radiographic images are acquired in rapid succession as the X-ray tube sweeps and rotates across the ROI. Once acquired, these projection images are subject to image processing that registers and reconstructs them into individual tomographic slices.

Tomosynthesis provides visualization of human anatomy by
1. Removing overlying anatomical structures, which could otherwise obscure a structure of interest by superimposition in a two dimensional presentation, and
2. Producing a number of slice images throughout the entire volume of the anatomy

The exceptionally high magnification capability (up to 5X) from the 0.02 mm focal spot with optimized cabinet geometry and the superior contrast available from the low kV capability provides enhanced film and/or digital imaging performance. This device supports radiographic film sizes up to 30 x 35 cm and can be

configured to acquire high resolution, DICOM compliant, digital x-ray images through the use of an integrated camera and Kubtec DIGICOM Specimen Radiography software.

To support the Tomosynthesis application, the predicate device, XPERT 40, has a low-voltage screw drive linear actuator installed in the enclosed head of the cabinet with the same 50 kVp monoblock X-ray tube as the predicate to allow motion of the X-ray source to capture the multiple projection images and the same CMOS detector mounted stationary in the bottom of the cabinet x-ray unit.

III. SUMMARY OF STUDIES AND SAFETY

Kubtec successfully completed internal and external safety testing requirements. (61010-1 3rd edition, 21 CFR 1020.40). The software validation and verification testing was also performed.

Compliance with Section 514 of the Food, Drug and Cosmetic Act

The device conforms to the requirements included in FDA Class II, Product Code MWP, 21 CFR 892.1680 Stationary X-ray Systems –Radiology Cabinet X-ray Systems/

Conformance to voluntary standards

The subject device conforms to the following standards:

- 21 CFR 1020.40 Performance Regulations for Ionizing Radiation - Cabinet x-ray systems
- IEC 61010-1 Edition 3.0 2010-06 - Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use - Part 1: General Requirements [Including: Corrigendum 1 (2011)]
- 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) DICOM (Digital Imaging and Communications in Medicine) 3.0
- ISO 15223-1 Second Edition 2012-07-01 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements
- IEC 62304:2006 Medical Device Software - Software Life Cycle Processes

IV. SUBSTANTIAL EQUIVALENCE

The Kubtec MOZART is substantially equivalent to the following currently cleared devices:

1. 510(k) Number: K071233 Trade Name: Kubtec XPERT 40

The proposed and predicate devices utilize similar technology and materials, comparable safety and effectiveness features, and is similar in design and construction and introduces no new safety issues. The Kubtec MOZART is as safe and effective as the predicate device (XPERT 40), the technological differences amount to the addition of a mechanism to move the x-ray source linearly and proprietary software to compile the multiple images captured and creates a composite image, 1mm slices, and a 2-D image. The Indications for Use and labeling are virtually the same or similar 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.

To support the Tomosynthesis application, the proposed device, MOZART, utilizes the predicate device, XPERT 40, having the addition of a low-voltage screw-drive linear actuator installed in the enclosed head of the cabinet, which ensures operator safety, with the same 50 kVp monoblock X-ray tube as the predicate to allow motion of the X-ray source to capture the multiple projection images and the same CMOS detector mounted stationary in the bottom of the same shielded cabinet x-ray unit with proprietary software installed into an off the shelf personal computer, Microsoft Windows 7 Operating System, and a 2 megapixel or greater portrait type monitor.

The workstation on the MOZART utilizes a more powerful GPU to facilitate the handling of the collected projection data. It utilizes a method of dynamically reconstructing 3D tomographic images from a set of projections images. This includes loading the set of projection images into memory, selecting a region of interest, applying any necessary preprocessing, selecting a reconstruction method reconstructing an image according to said reconstruction method to produce a 3D tomographic image focusing on said region of interest, performing any post reconstruction processing on the 3D tomographic image and rendering said 3D tomographic image on a display. US Patent US 8,233,690 B2 displaying the complete algorithm and process is included.

Indications for Use:

The MOZART (XPERT42) is a Cabinet x-ray system that is used to provide two dimensional and three dimensional tomographic digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

	Xpert 40	MOZART
TUBE POTENTIAL	10-50kV	10-50kV
FOCAL SPOT	<50µm	<50µm
TUBE CURRENT	Up to 1mA	Up to 1mA
INPUT POWER	90-250v AC, 50/60Hz, 500VA	90-250v AC, 50/60Hz, 500VA
DETECTOR SIZE	From 5x5 cm up to 20x20 cm	12 x 15 cm
FIELD OF VIEW	20 degree	20 degree
FILM COVERAGE	25 x 30 cm	25 x 30 cm
DETECTOR RESOLUTION	<48 µm/<96 µm	<48 µm
DETECTOR PIXELS	1024 x 1024 / 2048 x 2000	1536 x 1944
INTERIOR CHAMBER SIZE	32.2 W x 37.9 D x 36 H cm	32.2 W x 37.9 D x 36 H cm
EXTERIOR CABINET DIM	N/A	N/A
EXTERIOR CABINET DIM WITH CART	58.4 W x 58.4 D x 127.0 H cm	58.4 W x 58.4 D x 127.0 H cm
WEIGHT	N/A	N/A
WEIGHT WITH CART	250 lbs	250 lbs
MAXIMUM COVERAGE	25 cm x 30 cm	25 cm x 30 cm
MAXIMUM GEOMETRIC MAGNIFICATION	UP TO 5 TIMES	UP TO 5 TIMES
CLINICAL SOFTWARE	DIGICOM NORMAL	DIGICOM NORMAL / TomoSpec
SOFTWARE	DIGICOM NC with Pathology module	N/A
OPERATING SYSTEM	WINDOWS 7 PRO	WINDOWS 7 PRO

Technical Specifications – Mozart (XPERT42) vs Predicate XPERT 40

X-ray Tube – (Same as Predicate)
50 kVp 1mA
mono-block,
100% duty cycle,

25-50 kVp

20-1000µA

Tungsten Target
Beryllium Window

Detector - (Same type as Predicate) CMOS,
Active Area 11.4 x 14.6 cm,
Number of Pixels 2304 x 2940, 49.5µm pixel pitch, 2 fps

	MOZART Shad-o-Box 6K HS	Predicate XPERT40 Shad-o-Box 4K EV
Technology	Active-pixel CMOS	Active-pixel CMOS
Active Area	114 x 146 mm	99 x 96 mm
No. of Pixels	2304 x 2940	2048 x 2000
Pixel Size	49.5 µm	48 µm
A/D conversion	14-bit	14-bit
Dynamic range	73 dB	75 dB
Max. frame rate (full res)	9 fps	2.7 fps
PC Interface	GigE	LVDS
Overall dimensions	200 x 150 x 35 mm	264 x 208 x 19 mm
Full-well Capacity	850 ke	2000 ke
Fill Factor	79%	85%
Conversion Gain	52 e/DN	125 e/DN
Read Noise	180 e	250-350 e

Dark Current (23°C)	650 e/sec	3-5 ke/sec
Sensitivity (50kV, Min-R)	0.8 DN/µR	0.1 DN/µR
Rad. Hardness (160kVp)	>500 kR	<50 kR

SOD – 48.9 cm (Same as Predicate)
SDD - 50 cm (Same as Predicate)

V. CONCLUSION

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Heal. We conclude the subject device to be as safe and effective as the predicate devices based upon the clinical and non-clinical data summarized above. The Kubtec MOZART(XPERT42) is as safe and effective as the predicate device XPERT40, the technological differences amount to the addition of a mechanism to move the x-ray source linearly and proprietary software to compile the multiple images captured and create a composite image, 1mm slices, and a 2-D image. It has no new indications for use, thus rendering it substantially equivalent to the predicate device and conforms to applicable medical device safety standards.