KUB Technologies, Inc.                                      June 20, 2019
% Chester Lowe
Chief Technology Officer
111 Research Drive
STRATFORD CT 06615

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.


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,

[Signature]

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
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.

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
PRASStaff@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."
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.
111 Research Drive
Stratford, CT 06615 USA

Contact Person:

Name: Vikram Butani
Title: President
Telephone: +1.203.364.8544
Facsimile: +1.203.255.7494
Email Vbutani@kubtec.com

Name: Chester Lowe, Ph.D.
Title: Chief Technology Officer
Telephone: +1.203.364.8544
Facsimile: +1.203.255.7494
Email Clowe@kubtec.com

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 interest (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)]
- 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 are 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.
### 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

<table>
<thead>
<tr>
<th></th>
<th>XPERT 40</th>
<th>MOZART</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUBE POTENTIAL</td>
<td>10-50kV</td>
<td>10-50kV</td>
</tr>
<tr>
<td>FOCAL SPOT</td>
<td>&lt;50μm</td>
<td>&lt;50μm</td>
</tr>
<tr>
<td>TUBE CURRENT</td>
<td>Up to 1mA</td>
<td>Up to 3mA</td>
</tr>
<tr>
<td>INPUT POWER</td>
<td>90-250v AC, 50/60Hz, 500mA</td>
<td>90-250v AC, 50/60Hz, 500mA</td>
</tr>
<tr>
<td>DETECTOR SIZE</td>
<td>5x5 cm up to 20x20 cm</td>
<td>12 x 15 cm</td>
</tr>
<tr>
<td>FIELD OF VIEW</td>
<td>20 degree</td>
<td>20 degree</td>
</tr>
<tr>
<td>FILM COVERAGE</td>
<td>25 x 30 cm</td>
<td>25 x 30 cm</td>
</tr>
<tr>
<td>DETECTOR RESOLUTION</td>
<td>&lt;48 μm/-96 μm</td>
<td>&lt;48 μm</td>
</tr>
<tr>
<td>DETECTOR PIXELS</td>
<td>1024 x 1024 / 2048 x 2000</td>
<td>1536 x 1944</td>
</tr>
<tr>
<td>INTERIOR CHAMBER SIZE</td>
<td>32.2 W x 37.9 D x 36 H cm</td>
<td>32.2 W x 37.9 D x 36 H cm</td>
</tr>
<tr>
<td>EXTERIOR CABINET DIM</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>EXTERIOR CABINET DIM WITH CART</td>
<td>58.4 W x 58.4 D x 127.0 H cm</td>
<td>58.4 W x 58.4 D x 127.0 H cm</td>
</tr>
<tr>
<td>WEIGHT</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>WEIGHT WITH CART</td>
<td>250 lbs</td>
<td>250 lbs</td>
</tr>
<tr>
<td>MAXIMUM COVERAGE</td>
<td>25 cm x 30 cm</td>
<td>25 cm x 30 cm</td>
</tr>
<tr>
<td>MAXIMUM GEOMETRIC MAGNIFICATION</td>
<td>UP TO 5 TIMES</td>
<td>UP TO 5 TIMES</td>
</tr>
<tr>
<td>CLINICAL SOFTWARE</td>
<td>DIGICOM NORMAL</td>
<td>DIGICOM NORMAL / Tomospec</td>
</tr>
<tr>
<td>SOFTWARE</td>
<td>DIGICOM NC with Pathology module</td>
<td>N/A</td>
</tr>
<tr>
<td>OPERATING SYSTEM</td>
<td>WINDOWS 7 PRO</td>
<td>WINDOWS 7 PRO</td>
</tr>
<tr>
<td></td>
<td>MOZART Shad-o-Box 6K HS</td>
<td>Predicate XPERT40 Shad-o-Box 4K EV</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Technology</td>
<td>Active-pixel CMOS</td>
<td>Active-pixel CMOS</td>
</tr>
<tr>
<td>Active Area</td>
<td>114 x 146 mm</td>
<td>99 x 96 mm</td>
</tr>
<tr>
<td>No. of Pixels</td>
<td>2304 x 2940</td>
<td>2048 x 2000</td>
</tr>
<tr>
<td>Pixel Size</td>
<td>49.5 µm</td>
<td>48 µm</td>
</tr>
<tr>
<td>A/D conversion</td>
<td>14-bit</td>
<td>14-bit</td>
</tr>
<tr>
<td>Dynamic range</td>
<td>73 dB</td>
<td>75 dB</td>
</tr>
<tr>
<td>Max. frame rate (full res)</td>
<td>9 fps</td>
<td>2.7 fps</td>
</tr>
<tr>
<td>PC Interface</td>
<td>GigE</td>
<td>LVDS</td>
</tr>
<tr>
<td>Overall dimensions</td>
<td>200 x 150 x 35 mm</td>
<td>264 x 208 x 19 mm</td>
</tr>
<tr>
<td>Full-well Capacity</td>
<td>850 ke</td>
<td>2000 ke</td>
</tr>
<tr>
<td>Fill Factor</td>
<td>79%</td>
<td>85%</td>
</tr>
<tr>
<td>Conversion Gain</td>
<td>52 e/DN</td>
<td>125 e/DN</td>
</tr>
<tr>
<td>Read Noise</td>
<td>180 e</td>
<td>250-350 e</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>Dark Current (23°C)</td>
<td>650 e/sec</td>
<td>3-5 ke/sec</td>
</tr>
<tr>
<td>Sensitivity (50kV, Min-R)</td>
<td>0.8 DN/µR</td>
<td>0.1 DN/µR</td>
</tr>
<tr>
<td>Rad. Hardness (160kVp)</td>
<td>&gt;500 kR</td>
<td>&lt;50 kR</td>
</tr>
</tbody>
</table>

Shad-o-Box 6K HS vs. Shad-o-Box 4K EV
MTF (Min-R 2190)

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 Health. 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.