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

June 12, 2020

Re: K200756
Trade/Device Name: Kubtec MOZART SUPRA (XPERT 84) Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: May 8, 2020
Received: May 11, 2020

Dear Dr. 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 and Part 809); 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 T. 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)*
K200756

Device Name
Kubtec MOZART SUPRA (XPERT 84) Radiography System

Indications for Use *(Describe)*
The MOZART SUPRA Specimen Tomosynthesis System is a Cabinet x-ray system that is specifically designed to provide high detail radiographic imaging of surgically excised medical specimens from various anatomical regions, i.e. breast, both in 2-dimensional and 3-dimensional tomosynthesis views.

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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K200756

MOZART SUPRA(XPERT84)

Stationary X-ray System

510(k) Summary

KUB Technologies, Inc.

JUNE 2020

General Information

Submitter's Information

Applicant:

KUB Technologies, Inc.
111 Research Drive
Stratford, CT 06615 USA

Contact Person:

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Email	Clowe@kubtec.com

Establishment Number: KUB Technologies, Inc. # 3006051164

Identification of Devices:

Proprietary/Trade Name:	Kubtec MOZART SUPRA(XPERT84) Radiography System
Classification name:	Stationary X-ray System
Classification:	Class II
CFR Section:	21 CFR 892.1680
Product Codes:	MWP
Common Name:	Stationary X-ray System

Applicable Standards

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

Indications for Use

The MOZART SUPRA(XPERT84) Specimen Tomosynthesis System is a Cabinet x-ray system that is specifically designed to provide high detail radiographic imaging of surgically excised medical specimens from various anatomical regions, i.e. breast, both in 2-dimensional and 3-dimensional tomosynthesis views.

Device Description

The MOZART SUPRA(XPERT84) Specimen Radiography System is a Cabinet X-ray System specifically designed to provide 3-D high detail radiographic imaging of surgically excised medical specimens utilizing tomosynthesis.

The MOZART SUPRA(XPERT84) is a fully self-contained and shielded cabinet system equipped with a 90kVp micro-focus x-ray source and a 10" x 12" 49.5 micron high resolution CMOS Digital Detector.

- 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.

The exceptionally high magnification capability (up to 5X) from the 0.005 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 is configured to acquire high resolution, DICOM compliant, digital x-ray images through the use of an integrated camera and Kubtec DIGICOM Specimen Radiography software.

Specifications:

Cabinet	71 L x 76.2 W x 162.5 cm H
Dimensions - Interior	40.6 L x 33 W x 11.4 cm H)
Weight	800 lbs (363 kg)
Temperature Range (User Operation)	0-35 degrees C (32-95 F)
Humidity	10 – 80% R.H
Power Requirements	90-250v AC, 50/60Hz, 500VA
X-ray Source Specifications	
Maximum Potential	90 kVp
Maximum Current	0.25 mA
Total Wattage	0.5 kW
Focal Spot	5 µm nominal
Window Material	.005 in. Beryllium
Detector Specifications	
Type	CMOS
Imaging Area	23 cm x 29 cm
Pixel Size	49.5 µm - 10 lp/mm
Resolution	4608 X 5890
DQE	76% @ 1 lp/mm
Data Output/Dynamic Range	16-bits
Optical Camera Specifications	
Resolution	13 megapixel

Diagrams / Pictures / Drawings

Reprocessing, Cleaning, Disinfection, and Sterilization

The device is not sterile nor does it require sterilization.

Proposed Labels, Labeling, Advertisements, and Directions

Same as predicate

Summary of Safety and Effectiveness

Technological

KUB Technologies, Inc. believes that the subject device is substantially equivalent to other devices that have previously received US FDA 510(k) clearance including the predicate device.

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.

- Kubtec XPERT 40 (K071233)
- Kubtec MOZART(XPERT42) (K183624)

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

Electrical Safety and Electromagnetic Compatibility

Electrical safety and EMC testing were conducted on the MOZART SUPRA(XPERT84), consisting of the Cabinet System with it's operating computer. The system complies with the UL 61010-1 2012, UL 61010-1-12:2012, ul 61010-2-091, IEC 61326-1 2012/07/10 Ed: 2, IEC 61326-1 2012/07/10 Ed: 2 Japan and IEC 60601-2-37 standards for safety and the FCC 47CFR Part 15 Subpart B: 04/2019 standard for EMC.

The device complies with electrical safety standards that are applicable for this type of device including:

- 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

Software Verification and Validation Testing

The system utilizes proprietary KUBTEC DIGICOM software. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Bench and Clinical Studies

Images attained by the system have been read and verified by a Board Certified Radiologist to product diagnostic quality images.

Substantial Equivalence Discussion

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

510(k) Number: K183624 Trade Name: Kubtec MOZART
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.

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 and the predicates.

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 SUPRA, utilizes the predicate device, MOZART, having the following:

- addition of a low-voltage screw-drive linear actuator installed in the enclosed head of the cabinet, which ensures operator safety,
- with a 90 kVp monoblock X-ray tube versus the 50 kVp predicate to allow motion of the X-ray source to capture the multiple projection images and,
- a CMOS detector of a slightly larger size (10"x12") mounted stationary in the bottom of the same shielded cabinet x-ray unit versus the predicate 5" x 6"

- with proprietary software installed into an off the shelf personal computer, Microsoft Windows 10 Operating System, and a 2 megapixel or greater portrait type monitor.

	Xpert 40	MOZART XPERT 42	MOZART SUPRA XPERT 84
TUBE POTENTIAL	10-50kV	10-50kV	40-90kV
FOCAL SPOT	<50µm	<50µm	<30µm
TUBE CURRENT	Up to 1mA	Up to 1mA	Up to 0.25mA
INPUT POWER	90-250v AC, 50/60Hz, 500VA	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	23 X 29 cm
FIELD OF VIEW	20 degree	20 degree	45 degree
FILM COVERAGE	25 x 30 cm	25 x 30 cm	25 x 30 cm
DETECTOR RESOLUTION	<48µm/<96µm	<48µm	<49µm
DETECTOR PIXELS	1024 x 1024 / 2048 x 2000	1536 x 1944	4608 x 5890
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	40.6 W X 33 D X 11.4 H cm
EXTERIOR CABINET DIMENSION	N/A	N/A	N/A
EXTERIOR CABINET DIMENSION WITH CART	58.4 w x 58.4 D 127 H cm	58.4 w x 58.4 D 127 H cm	71.1 w x 76.2 D x 162.5 H cm
WEIGHT	N/A	N/A	N/A
WEIGHT WITH CART	250lbs	250lbs	800lbs
MAXIMUM COVERAGE	25 cm x 30 cm	25 cm x 30 cm	25 cm x 30 cm
MAXIMUM GEOMETRIC MAGNIFICATION	up to 5 times	up to 5 times	up to 5 times
CLINICAL SOFTWARE	DIGICOM NORMAL	DIGICOM NORMAL / TomoSpec	DIGICOM NORMAL / TomoSpec
SOFTWARE	DIGICOM NC with Pathology module	N/A	DIGICOM NC with Pathology module
OPERATING SYSTEM	WINDOWS 7 PRO	WINDOWS 7 PRO	WINDOWS 10 PRO

Conclusion

The Kubtec MOZART SUPRA(XPERT84) is as safe and effective as the predicate device, the technological differences amount to the addition of a higher energy x-ray source (30-90 kVp) and a larger detector (23cm x 29cm). It has no new indications for use, thus rendering it substantially equivalent to the predicate device and conforms to applicable medical device safety standards.