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

September 20, 2021

Re: K210955
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: August 27, 2021
Received: August 30, 2021

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); 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)*
K210955

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 used to provide 2-dimensional and 3-dimensional tomographic digital X-ray images of harvested specimens from various anatomical regions.

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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Kubtec MOZART SUPRA (XPERT 84)
Premarket Notification 510(k) Summary
K210955

Identification of Devices:

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

Applicant:

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

Contact Person:

Name:	Chester Lowe, Ph.D.
Title:	Chief Technology Officer
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Email	CLowe@kubtec.com

Establishment Number: KUB Technologies, Inc. # 3006051164

I. INDICATIONS FOR USE

The MOZART® Supra® Specimen Tomosynthesis System is a cabinet X-ray system that is used to provide 2-dimensional and 3-dimensional tomographic digital X-ray images of harvested specimens from various anatomical regions.

II. DEVICE DESCRIPTION

The MOZART SUPRA (XPERT84) 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.

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, MOZART SUPRA (XPERT84), K200756, 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 an Amorphous Selenium 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 to the following standards The software and verification testing was also performed.

The Proposed MOZART SUPRA (XPERT84) with a-Se detector was successfully tested by INTERTEK to IEC 61010-1 Safety requirements for electrical equipment for

measurement, control, and laboratory use - Part 1: General requirements as well to EMC Directive 2004/108/EC

Design controls and design transfer with appropriate risk management and analysis have been maintained per ISO 13485:2016, KUBTEC's Standard Operating Procedures via Quality and Regulatory Assurance (QARA) and Engineering, 21 CFR Part 820, and to 21 CFR 1020.40.

Agency	Standard	Recognition Number	Description
IEC	60601-1-2	19-36	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC	60601-1-10	19-37	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
IEC	60601-1-11	19-38	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC	60601-1-12	19-39	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC	61010-1	19-34	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC	62304 1st Ed	13-79	Medical device software - Software life cycle processes
ISO	14971 2nd Ed	5-40	Medical devices - Application of risk management to medical devices
ISO	15223-1	5-117	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
IEC	61910-1 1st Ed	12-290	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy

NEMA	PS 3.1 - 3.20	12-300	Digital Imaging and Communications in Medicine (DICOM) Set
CFR	21 CFR 1020.40	N/A	Cabinet X-Ray Systems

IV. BASIS FOR THE SUBMISSION

The XPERT 84 Specimen Radiography System is a fully shielded Cabinet X-ray System that has been designed to comply with 21 CFR 1020.40. The system allows more than 20 times geometric magnification of excised specimens with minimal geometric distortion through the use of a focal spot size that is less than 20 microns. The x-ray coverage of the device allows the use of radiographic film sizes up to 35 x 43 cm. The device can also be configured to provide high resolution, DICOM compliant, digital images through the use of an integrated digital camera and Kubtec DIGICOM Specimen Radiography software. The Kubtec DIGICOM Software supports the DICOM Store, Print and Modality Worklist functionalities.

This device, MOZART SUPRA (XPERT84) will include a modification/replacement of the detectors in previously approved devices and functionally identical to the predicate devices. (See specifications in Section V) CMOS detector to an Amorphous SILICON detector

There is no change for the indication for use for the previously 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. SUBSTANTIAL EQUIVALENCE

The Kubtec MOZART SUPRA(XPERT84) Specimen Radiography System equipped with the Amorphous Selenium detector is substantially equivalent to the following currently cleared devices:

PRIMARY:
510(k) Number: K200756 Trade Name: Kubtec MOZART SUPRA (XPERT84) Specimen Radiography System

SECONDARY:
510(k) Number: K 111508 Trade Name: Hologic TRIDENT SPECIMEN RADIOGRAPHY
510(k) Number: K 193166 Trade Name: Siemens MAMMOMAT Revelation

Predicate Device:

Device Name:	Kubtec MOZART SUPRA (XPERT84)
510(k) Number:	K200756
Classification	Class: II
Regulation Number:	21 CFR 892.1680
Product Code:	MWP
Regulation Name:	Stationary X-ray System

Device Name:	Hologic TRIDENT SPECIMEN RADIOGRAPHY SYSTEM Model:RC
510(k) Number:	K111508
Classification	Class: II
Regulation Number:	21 CFR 892.1680
Product Code:	MWP
Regulation Name:	Stationary X-ray System

Device Name:	Siemens MAMMOMAT Revelation
510(k) Number:	K193166
Classification	Class: II
Regulation Number:	21 CFR 892.1715
Product Code:	MUE
Regulation Name:	Full-field digital mammography system

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.

Both systems produce digital images which can be sent to hardcopy printers, softcopy diagnostic workstations and/or stored in archive.

The proposed MOZART SUPRA(XPERT84) Specimen Radiography System, utilizes the predicate devices, MOZART SUPRA(XPERT84) Specimen Radiography System, with the same 90 kVp monobloc X-ray tube installed in the enclosed head of the cabinet as the predicate and both the Hologic TRIDENT(Predicate 2) and the proposed XPERT 84 Specimen Radiography System utilizes the Amorphous Selenium detector mounted stationary in the bottom replacing the predicate CMOS detector of the same shielded cabinet x-ray unit 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.

The performance of the proposed AXS-2430V2 detector has been verified and cleared via 510k K193166 as incorporated into the Siemens MAMMOMAT Revelation.

Both systems utilize the same DIGICOM software.

The "Level of Concern" of MOZART SUPRA (XPERT 84) Specimen Radiography System software (DIGICOM) is **"moderate"**

The previous claims have been proven internally and validated and verified via imaging of line-pair gauges and phantoms.

They have been clinically validated by reads of excised breast biopsies by a board certified radiologist.

DETECTORS					
	Currently Approved KUBTEC K200756		Proposed		HOLOGIC APPROVED K111508
	Manufacturer		Manufacturer		Manufacturer
	Rad-Icon		Analogic		Hologic
MFR Model #	6K	2329	AXS-1824V2	AXS-2430V2	1214
KUBTEC SKU	DV136	DV266	DV210	DV270	n/a
Type	Active Pixel CMOS	Active Pixel CMOS	Amorphous Selenium	Amorphous Selenium	Amorphous Selenium
Detection Method	In-direct	In-direct	Direct	Direct	Direct
Size (cm)	11.4 x 14.5	22.8 x 29.1	17.4 x 23.9	23.9 x 30.5	12 x 14
Resolution	49.5µm	49.5µm	85µm	85µm	70µm
Pixel size	2304 x	4608 x 5890	2048 x 2816	2816 x 3584	2285 x 2571

	2940				
DQE 1 Lp/mm	>45%	>55%	>50%	>70%	>55%
MTF 1 Lp/mm	>80%	>85%	>90%	>95%	>90%
Bit Depth	16 bits	16 bits	16 bits	16 bits	14 bits

Detector Specifications

Radiographic Magnification: 1.0x to 5x
Exposure Control: Automatic or Manual
X-ray Duty Cycle: 100%

Radiation Safety - 21CFR1020.40
Radiation shielded cabinet
Compartment door equipped with dual safety interlocks

Radiation leakage:
Less than 0.1 mR/hr at 5 cm from any exterior surface at maximum kV.

VI. CONCLUSION

The Kubtec MOZART SUPRA (XPERT84) is as safe and effective as the predicate and previously approved MOZART SUPRA (XPERT84) devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices and conforms to applicable medical device safety standards.