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

August 31, 2021

Re: K210957
Trade/Device Name: Kubtec Xpert 80 Specimen Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: August 1, 2021
Received: August 11, 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,

Michael D. O'Hara 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)*
K210957

Device Name
KUBTEC XPERT 80 Specimen RADIOGRAPHY SYSTEM

Indications for Use *(Describe)*
The Kubtec XPERT 80 is a Cabinet x-ray system that is used to provide film and/or digital x-ray images of harvested specimens from various regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

It is not used for mammography

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.

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XPERT 80
Premarket Notification 510(k) Summary
K210957

Date: August 20, 2021

Identification of Devices:

Proprietary/Trade Name:	Kubtec XPERT 80 Specimen 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
Telephone: +1.203.364.8544
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Email CLowe@kubtec.com

Establishment Number: KUB Technologies, Inc. # 3006051164

SUBSTANTIAL EQUIVALENCE

The proposed Kubtec XPERT 80 Specimen Radiography System is substantially equivalent to the following currently cleared devices:

1. 510(k) Number: K071233 Trade Name: Kubtec XPERT 40/80/80L Specimen Radiography System (primary predicate)
2. 510(k) Number: K 111508 Trade Name: Hologic TRIDENT SPECIMEN RADIOGRAPHY
3. 510(k) Number: K 193166 Trade Name: Siemens MAMMOMAT Revelation

The only difference between the predicate to the Kubtec XPERT 40/80/80L Specimen Radiography System K071233 is the addition of the Amorphous Selenium detector and imaging qualities are exhibited by predicates 2 and 3.

DEVICE DESCRIPTION

The XPERT 80 Specimen Radiography System is a Cabinet X-ray System specifically designed to provide high detail radiographic imaging of surgically excised medical specimens. 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. It has been designed to comply with 21 CFR 1020.40.

DEVICE TECHNICAL DESCRIPTION

	Xpert 80 (Predicate)	**Xpert 80 (Proposed)**
TUBE POTENTIAL	90kV	90kV
FOCAL SPOT	<5µm	<5µm
TUBE CURRENT	.178	.178
INPUT POWER	90-250v AC, 50/60Hz, 500VA	90-250v AC, 50/60Hz, 500VA
DETECTOR TYPE	CMOS	Amorphous Selenium
DETECTOR SIZE	22.8 x 29.1 cm	23.9 x 30.5 cm
FIELD OF VIEW	45 degree	45 degree
DETECTOR RESOLUTION	49.5 µm	85 µm
DETECTOR PIXELS	4608 x 5890	2816 x 3584
INTERIOR CHAMBER SIZE	35.6 W x 43.2 D x 45.7 H cm	35.6 W x 43.2 D x 45.7 H cm

EXTERIOR CABINET DIM WITH CART	76.2 W x 61.0 D x 152.4 H cm	76.2 W x 61.0 D x 152.4 H cm
WEIGHT	250 lbs	250 lbs
WEIGHT WITH CART	400 lbs	400 lbs
MAXIMUM GEOMETRIC MAGNIFICATION	MORE THAN 5 TIMES	MORE THAN 5 TIMES
SOFTWARE	DIGICOM 11	DIGICOM 11
OPERATING SYSTEM	WINDOWS 10 PRO	WINDOWS 10 PRO

SYSTEM DESCRIPTION

DETECTORS			
	Currently Approved KUBTEC K071233	Proposed	HOLOGIC APPROVED K111508
	Manufacturer	Manufacturer	Manufacturer
	Rad-Icon	Analogic	Hologic
MFR Model #	2329	AXS-2430V2	1214
KUBTEC SKU	DV266	DV270	n/a
Type	Active Pixel CMOS	Amorphous Selenium	Amorphous Selenium
Detection Method	In-direct	Direct	Direct
Size (cm)	22.8 x 29.1	23.9 x 30.5	12 x 14
Resolution	49.5µm	85µm	70µm
Pixel size	4608 x 5890	2816 x 3584	2285 x 2571
DQE 1 Lp/mm	>55%	>70%	>55%
MTF 1 Lp/mm	>85%	>95%	>90%
Bit Depth	16 bits	16 bits	14 bits

Radiographic Magnification: 1.0x to 10x
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.

INDICATIONS FOR USE

The Kubtec XPERT 80 is a Cabinet x-ray system that is used to provide film and/or digital x-ray images of harvested specimens from various regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

It is not used for mammography

COMPARISON TO PREDICATE DEVICE

The Kubtec XPERT80 Specimen Radiography System equipped with the Amorphous Selenium detector is substantially equivalent to the following currently cleared devices:

510(k) Number: K071233 Trade Name: Kubtec XPERT 40/80/80L Specimen Radiography System (primary predicate)
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 XPERT 40/80/80L SPECIMEN RADIOGRAPHY SYSTEM
510(k) Number:	K071233
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 XPERT 80 Specimen Radiography System, utilizes the predicate devices,XPERT 80 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 80 Specimen Radiography System utilize the Amorphous Silicon 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 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 XPERT 80 Specimen Radiography System software (DIGICOM) is **“moderate”**

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 XPERT 80 Specimen Radiography System 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

CONCLUSION:

The Kubtec proposed KUBTEC XPERT 80 Specimen Radiography System equipped with an Amorphous Selenium Detector is as safe and effective as the predicate device, the technological differences amount to the change of the type of detector to produce the 2-D x-ray 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.