Faxitron Bioptics, LLC
% Mr. Douglas Wiegman
VP Engineering
3440 E. Britannia Drive, Suite 150
TUCSON AZ 85706

May 9, @018

Re: K173309
Trade/Device Name: Faxitron VisionCT
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: March 30, 2018
Received: April 2, 2018

Dear Mr. Wiegman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INIDCATIONS FOR USE STATEMENT

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)*
K173309

Device Name
Faxitron VisionCT

Indications for Use *(Describe)*
The Faxitron VisionCT is a Cabinet x-ray system that is used to provide two and three dimensional 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. Doing the verification directly in the same room or nearby enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

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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Premarket Notification 510(k) Summary

(As required by 21 CFR 807.92)

Device name - as required by 807.92(a)(2):

Trade Name:	Faxitron VisionCT
Common/ Classification Name:	Specimen X-ray System/ Cabinet X-Ray System
Classification Regulation:	21 CFR 892.1680
Device Class:	Class II
Product Code:	MWP
Panel:	Radiologic Devices Panel
Company Name: [as required by 807.92(a)(1)]	Faxitron Bioptics, LLC Company Address: 3440 East Britannia Drive, Suite150 Tucson, Arizona 85706 Contact: Ciaran Purdy, VP of Development
Preparation Date:	March 30, 2018

LEGALLY MARKETED PREDICATE DEVICES - as required by 21 CFR 807.92(a)(3)

The Faxitron VisionCT is substantially equivalent to following predicate devices:

A. Faxitron VersaVision Specimen Radiography System (K170786)
B. Faxitron BioVision Plus Specimen Radiography System (K153583)
C. XPERT 40 Specimen Radiography System (K071233)

DEVICE DESCRIPTION - as required by 21 CFR 807.92(a)(4)

The Faxitron VisionCT is specially designed for high detail radiographic imaging of surgically excised medical specimens. It is a fully shielded Cabinet X- ray System that has been designed to comply with 21 CFR 1020.40. It allows up to 4.0 times geometric magnification of excised specimens with minimal geometric distortion through the use of a focal spot size that is less than 15 microns. With optimized cabinet geometry and the superior contrast available from the low kV capability, the VisionCT provides enhanced image performance. It is configured to acquire high resolution digital images up to 15 x 15 cm in size, through the use an integrated detector and Faxitron Vision Specimen Radiography software. The Faxitron Software supports the DICOM Store, Print and Modality Worklist services.

DEVICE TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4)

X-Ray Tube

Focal spot size	< 15 um
kV	15-50kV
mA	1.0mA max
Power	iso-watt limited to 11.5W max
Beryllium window thickness	0.010 “ (254um)
X-ray beam divergence	40 deg. min.
Target Material	Tungsten (W)

Radiographic Magnification: 1.2X to 4X
Exposure Control: Automatic or Manual
X-ray Duty Cycle: 75%
Power Requirements: 100 - 240 VAC, 50/60 Hz, 200VA Max

Radiation Safety
Radiation shielded cabinet
Compartment door equipped with dual safety interlocks
Radiation: Less than 0.1 mR/hr at 5 cm (2 in.) from exterior surface at maximum kV

INTENDED USE - as required by 807.92(a)(5)

The Faxitron VisionCT is a Cabinet x-ray system that is used to provide two and three dimensional 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. Doing the verification directly in the same room or nearby enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

TECHNOLOGICAL CHARACTERISTICS SUMMARY- as required by 807.92(a)(6)

The technological characteristics of the VisionCT are also comparable to the predicate devices as shown below.

	Subject Device	**Predicate Device**	**Predicate Device**	**Predicate Device**
Device/ Model	**Faxitron VisionCT Specimen Radiography System**	**VersaVision Specimen Radiography System**	**XPERT 40 Specimen Radiography System**	**BioVision Plus**
Manufacturer	**Faxitron Bioptics LLC**	**Faxitron Bioptics LLC**	**Kub Technologies Inc**	**Faxitron Bioptics LLC**
510(k) #	**N/A**	**K170786**	**K071233**	**K153583**
Detectors	Xineos-1515 (by Teledyne DALSA)	Faxitron DC105, DC0615, DC1215 and DC1524	Not Specified	Faxitron DC1215
Film Capable	No	Yes	Yes	No
Digital Capable	Yes	Yes	Yes	Yes
CT Reconstruction Option	Yes	No	No	No
Detector sizes	15x15 cm	10 x 15 cm, 6 x15 cm, 12 x 15 cm, 15 x 24 cm	12 cm x 15 cm 20 cm x 20 cm	12 cm x 15 cm
Detector Resolution (contact)	5 lp/mm	10 & 20 lp/mm	10, 15, & 20 lp/mm	20 lp/mm
Magnification Range	1.2X to 4X	1X to 8X	5X	1X to 3X
X-ray Tube • Focal spot • Window Thickness	< 15 µm 0.010” Beryllium	< 15 µm 0.010” Beryllium	50 µm 0.005” Beryllium	< 15 µm 0.010” Beryllium
X-ray Tube Target Material	Tungsten	Tungsten	Not specified	Molybdenum
Tube Voltage Range	15-50 kV	15-50 kV	10-50 KV	20-50 kV
Tube Current	Up to 1.0 mA	Up to 1.0 mA	Up to 1.0 mA	Up to 1.0 mA
Time Range	0 to 900 seconds	0 to 300 seconds	Not specified	0 to 20 seconds
X-ray coverage	15 x 15 cm	Up to 15 x 24 cm	12 cm x 15 cm 20 cm x 20 cm	12 x 15 cm
DICOM compliant	Yes	Yes	Yes	Yes
Power Ratings	100 – 240 VAC, 50/60 Hz, 200VA	100 - 240 VAC, 50/60 Hz, 150VA	90-250 VAC, 50/60 Hz, 500VA	100 - 240 VAC, 50/60 Hz, 150VA
Dimensions (cm)	21 W x 17 D x 25 H	53 W x 61 D x 77 H	58 W x 58 D x 127 H	56 W x 57 D x 170 H
Weight (kg)	60	77	136	90

Fundamentally, the Faxitron VisionCT is the same as the referenced predicate devices in that it is a cabinet X-Ray system with the X-tube and digital CMOS Detector. Like the predicate devices, the Faxitron VisionCT is a cabinet x-ray system that is used to provide 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. Like the VersaVision, the VisionCT only provides digital x-ray images (no film images).

The major difference between the identified predicate devices and the proposed Faxitron VisionCT is that in addition to the digital 2D x-ray images, the VisionCT also provides digital 3D x-ray images. The referenced predicate devices image top down (vertically); whereas, the VisionCT images horizontally. See Figure 4 and Figure 5 below comparing the operating principle. The horizontal imaging allows for the specimen to be rotated so images can be captured in 360 degrees. These images are then reconstructed to a 3D CT image. The capability of providing digital 3D x-ray images is a progression in technology and not a new intended use.

The Faxitron VisionCT uses Detector XINEOS-1515 (by Teledyne DALSA), which is different compared to those used in predicate devices. However, a detector with the same technological characteristics has been used in the previously cleared DENTRIα Series device (K160140).

The commercial name of the software used in VisionCT is called Faxitron Bioptics Vision Software. This Vision Software is upgraded from the software used in the predicate device VersaVision Specimen Radiography System (K170786). The upgrades mainly relate to the changes made to GUI and to support the features of the VisionCT. Faxitron has thoroughly tested the Vision Software including the added capability for providing 3D X-ray images.

<u>NONCLINICAL PERFORMANCE DATA TESTING AND REVIEW- as required by 807.92(b)(1)</u>

The VisionCT complies with 21 CFR 1020.40 (Cabinet x-ray systems) and NEMA PS 3.1 - 3.20 (DICOM). The non-clinical performance testing data provided in this submission includes detector Xineos 1515 imaging performance data and sample clinical images to demonstrate the capability of the VisionCT to image various anatomical regions (breast tissue, femoral head, other tissues such as fallopian tube, prostate, nasal polyp, and heat valve).

The phantom images include those provided to compare the 2D images from the predicate device and 3D images from the subject device. In addition, a uniform phantom and phantom with embedded test objects with ranges of sizes and contrasts designed to characterize CT x-ray system contrast and

detail imaging performance, are also provided. Also, Faxitron provided data obtained from the artifact analysis on these sample clinical and phantom images.

The Electrical Safety of the Faxitron VisionCT is demonstrated through successful testing conducted per IEC 61010-1, IEC 61010-2-091, and IEC 61010-2-101. The Electromagnetic Compatibility was demonstrated through compliance with standards IEC 61326-1 and IEC 61326-2-6.

CONCLUSIONS- as required 807.92(b)(3)

Faxitron Bioptics concludes that the documentation and testing included in this submission indicates that the Faxitron VisionCT is safe and effective and substantially equivalent to the cited predicate devices.