Faxitron Bioptics, LLC
% Ciaran Purdy
VP of Development
3440 E. Britannia Dr., Suite 150
TUCSON AZ 85706

March 14, 2019

Re: K183142
Trade/Device Name: PathVisionXL
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: February 15, 2019
Received: February 19, 2019

Dear Ciaran Purdy:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K183142

Device Name
PathVisionXL

Indications for Use *(Describe)*

The PathVisionXL is a Cabinet x-ray system that is used to provide film and/or 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

K183142

(As required by 21 CFR 807.92)

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

Trade Name:	PathVisionXL
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:	October 3, 2018

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

The Faxitron PathVisionXL is substantially equivalent to following predicate device:

A. Faxitron PathVision Specimen Radiography System (K122428)

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

The PathVisionXL 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. The larger (XL) cabinet allows up to 10.0 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 PathVisionXL provides enhanced image performance. It is designed to acquire a large high resolution digital images up to 43 x 43 cm in size, through the use an integrated digital X-Ray detector and Faxitron Vision 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	20-100kV
mA	0.3mA max
Power	Iso-watt limited to 12W max
Beryllium window thickness	0.010 “ (254um)
X-ray beam divergence	40 deg. min.
Target Material	Tungsten (W)

Radiographic Magnification: 1.0x to 10x
Exposure Control: Automatic or Manual
X-ray Duty Cycle: 50%
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 PathVisionXL is a Cabinet x-ray system that is used to provide film and /or 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 PathVisionXL has the same indications for use, general configuration, and principles of operation as the predicate device listed above. The technological characteristics of the PathVisionXL have been compared to the predicate device cited and is covered in detail in the Substantial Equivalence section of the submission.

Fundamentally, the PathVisionXL is the same as the referenced predicate device in that it is a cabinet X-Ray system with the X-tube and digital CMOS Detector. Like the predicate device, the PathVisionXL is used to provide 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. The major difference between the identified predicate device and the proposed PathVisionXL is the larger chamber size and X-Ray detector.

The ‘Level of Concern’ of PathVisionXL software is **"moderate"** and applicable software documentation is provided in the submission

NONCLINICAL PERFORMANCE DATA TESTING AND REVIEW- as required by 807.92(b)(1)

The PathVisionXL complies with 21 CFR 1020.40 (Cabinet x-ray systems) and following safety, EMC and performance standards:

- IEC 61010-1:2010 (Third edition), Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2-091:2012, Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-091: Particular requirements for cabinet X-ray systems
- IEC 61010-2-101:2015, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61326-1:2012, Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements
- IEC 61326-2-6:2012, Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements
- NEMA PS 3.1 - 3.20 (2016), Digital Imaging And Communications In Medicine Set

CONCLUSIONS- as required 807.92(b)(3)

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