DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 18, 2017

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

Re: K170786
Trade/Device Name: VersaVision
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: June 22, 2017
Received: June 23, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170786

Device Name
VersaVision

Indications for Use *(Describe)*

The **VersaVision** 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.

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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:	**VersaVision**
Common/Classification Name:	Specimen x-ray System/Cabinet X-ray System
Classification Regulation:	21 CFR 892.1680
Device Class:	Class II
Product Code (Precode):	MWP
Panel:	Radiologic Devices Panel
Company Name:	Faxitron Bioptics, LLC
Company Address:	3440 East Britannia Drive, Suite150 Tucson, Arizona 85706
Contact:	Douglas C. Wiegman, VP Engineering
Preparation Date:	July 13, 2017

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

The Faxitron VersaVision Digital Specimen Radiography System is substantially equivalent to the following predicate devices:

A. Faxitron BioVision Plus Specimen Radiography System (K153583)
B. Bioptics BioVision Specimen Radiography System (K091558)
C. Faxitron PathVision Specimen Radiography System (K122428)

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

The Faxitron VersaVision 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 8X) from the <15 micron 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 15 x 24 cm and can be configured to acquire high resolution, DICOM compliant, digital x-ray images up to 15 x 24 cm in size through the use an integrated detector and Faxitron Vision Specimen Radiography software.

DEVICE CLAIMS - as required by 807.92(a)

The Faxitron VersaVision 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 up to 8 times geometric magnification of excised specimens with minimal geometric distortion through the use of a focal spot size that is less than 15 microns. The x-ray coverage of the device allows the use of radiographic film sizes up to 15 x 24 cm. The device can also be configured to provide high resolution, DICOM compliant, digital images through the use an integrated digital camera that is up to 15 x 24 cm in size, 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)

Cabinet Specifications:
Energy Range: 15-50 kV Constant Potential
Tube Current: 1.0 mA max, iso-watt limited to 11.5 watts
Focal Spot Size: < 15 microns, 50 micron optional
X-ray beam divergence: 40 deg Min.
Optional divergence 23 deg. Min.
Target material: Tungsten
Beryllium Window Filtration: 0.010"
X-ray Coverage: 30 x 30 cm
Power: 100 - 240 VAC, ±10%, 50/60 Hz, 150 VA
Dimensions:
External: 21" W x 24" D x 30" H
Internal: 12" W x 12" D x 14" H
Weight: 170 lbs.

Digital System Specifications:
Active image Area: 15 x 24 cm
Options: 6 x 15 cm, 12 x 15 cm, 10 x 15 cm
Typical Spatial resolution: 10-20 lp/mm depending on detector
DICOM 3.0 compliant software includes Store, Print and Modality Work list
Network ready workstation and monitor included

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

Indications for Use: The VersaVision 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.

LEVEL OF CONCERN - as required by recent FDA guidance
Faxitron has determined that the submitted device has a **"moderate"** software **Level of Concern** and has provided a documented record as part of this submission.

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

The VersaVision Specimen Radiography System has the same indications for use, general configuration, and principles of operation as the predicate devices listed above. The technological characteristics of the VersaVision Specimen Radiography System have been compared to the predicate devices sited and is covered in detail in the Substantial Equivalence section of this submission.

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

The VersaVision Specimen Radiography System is a Cabinet X-ray System and has been designed and tested to comply with the performance standards set forth in 21 CFR 1020.40 Cabinet X-ray Systems and Laser performance standards 21 CFR1040.10 and 21 CFR 1040.11. Testing and performance data pertaining to these standards has been included as part of the submission. This device has also been successfully tested to the European EMC Directive and Safety testing to IEC 61010 third edition.

Substantial Equivalence Summary

The VersaVision Specimen Radiography System has the same indications for use as the predicate devices sited. The technical characteristics of the VersaVision are very similar to the predicate devices. The x-ray tube and detector technologies used in the VersaVision are the same as that used in the predicate devices. One major difference that we believe allows the VersaVision Radiography System to perform better than the predicate devices sited is the size of the focal spot (<15 microns), greater size of the digital detector and the optimized cabinet geometry which allows greater x-ray coverage and higher geometric magnification of excised specimens with minimal geometric distortion.

CONCLUSIONS- as required 807.92(b)(3)

We conclude that the documentation and testing included in this submission indicates that the VersaVision Specimen Radiography System is safe and effective and substantially equivalent to the predicate devices sited.