

K122428

SEP 25 2012



Premarket Notification 510 (k) Summary  
As required by 21 CFR 807.92

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

Trade Name: PathVision Specimen Radiography System

Common/Classification Name: Specimen x-ray System/Cabinet X-ray System

Classification Regulation: 21 CFR 892.1680

Device Class: Class II

Product Code (Procode): MWP

Panel: Radiologic Devices Panel

Company Name: Faxitron Bioptics, LLC

Company Address: 3440 East Britannia Drive, Suite 150  
Tucson, Arizona 85706

Contact: Douglas C. Wiegman,  
VP Engineering

Preparation Date: August 5, 2012

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

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

- A. Hologic Trident Specimen Radiography System (K111508)
- B. Faxitron Specimen Radiography System Model MX20 (K072557)
- C. Bioptics BioVision Digital Specimen Radiography System (K091558)

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

The Faxitron PathVision 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 6X) 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 35 x 35 cm and can be configured to acquire high resolution, DICOM compliant, digital x-ray images up to 23 x 29 cm in size through the use of an integrated camera and Faxitron Specimen Radiography software.

**DEVICE CLAIMS – as required by 807.92(a)**

The Faxitron PathVision 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 6 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 35 cm. The device can also be configured to provide high resolution, DICOM compliant, digital images through the use of an integrated digital camera that is up to 23 x 29 cm in size, and Faxitron 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: 10-100 kV Constant Potential
- Tube Current: 0.3 mA from 10 kV to 40 kV, iso-watt limited to 12 watts from 40 to 100 kV
- Focal Spot Size: < 20 microns
- X-ray beam divergence: 44 deg. Min.
- Target material: Tungsten
- Beryllium Window Filtration: 0.010"
- X-ray Coverage: 35 x 35 cm
- Power: 100 - 240 VAC, ±10%, 50/60 Hz, 200 VA
- Dimensions:
  - External: 23" W x 21" D x 36" H
  - Internal: 15.4" W x 15.4" D x 22.2" H
- Weight: 413 lbs.

## DEVICE TECHNICAL SPECIFICATION cont.

### Digital System Specifications:

- Active image Area: 23 x 29 cm  
Options: 18 x 20 cm
- Typical Spatial resolution: 7-10 lp/mm
- DICOM 3.0-compliant software includes Store, Print and Modality Worklist
- Network ready workstation and monitor included

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

Indications for Use: The PathVision 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 that documented record as part of this submission.

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

The PathVision 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 PathVision Specimen Radiography System have been compared to the predicate devices cited 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 PathVision 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. Testing and performance data pertaining to this standard has been included as part of the submission. This device has also been successfully tested to the European EMC Directive and will undergo Safety testing to IEC 61010 prior to being placed on the market.

## Substantial Equivalence Summary

The PathVision Specimen Radiography System has the same indications for use as the predicate devices sited. The technical characteristics of the PathVision are very similar to the predicate devices. One major difference that we believe allows the PathVision Radiography System to perform better than the predicate devices sited is the size of the focal spot (<20 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 PathVision Specimen Radiography System is safe and effective and substantially equivalent to the predicate devices sited.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

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

SEP 25 2012

Re: K122428  
Trade/Device Name: PathVision  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: MWP  
Dated: August 7, 2012  
Received: August 9, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

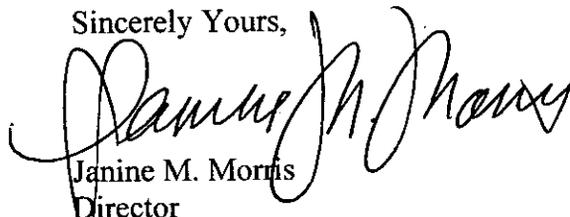
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris  
Director

Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number (if known): **K122428**

Device Name: **PathVision**

Indications for Use:

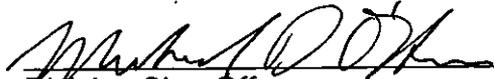
The **PathVision** is a Cabinet x-ray system that is used to provide film and/or digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure. Doing the verification directly in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

Prescription Use   ✓   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
\_\_\_\_\_  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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