



Food and Drug Administration  
10903 New Hampshire Avenue  
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April 1, 2016

Faxitron Bioptics LLC  
% Mr. Carlos Reyes  
Quality Consultant  
3440 E. Britannia Drive, Suite 150  
TUCSON AZ 85743

Re: K153583

Trade/Device Name: Biovision (Plus/+) Digital Specimen Radiography (DSR) System  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: MWP  
Dated: March 7, 2016  
Received: March 8, 2016

Dear Mr. Reyes:

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 yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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

## Indications for Use

510(k) Number (if known)  
K153583

Device Name  
BioVision (Plus/ +) Digital Specimen Radiography (DSR) System

### Indications for Use (Describe)

The BioVision (Plus/ +) Digital Specimen Radiography (DSR) System is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of harvested specimens from various anatomical regions, and to provide rapid verification that the correct tissue has been excised. Performing the verification directly in the same biopsy procedure room 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. This device is intended to be operated wherever the medical professionals deem appropriate, including a surgical suite or a room adjacent to a surgical suite.

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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**EXHIBIT 1**

**510(k) SUMMARY**

**PREMARKET NOTIFICATION 510(k) SUMMARY**  
**As required by CFR 807.92**

**Device Name – as required by 807.92(a)(2):**

Trade Name: **BioVision(Plus/+) Digital Specimen Radiography (DSR) System**

Common/Classification Name: **Stationary x-ray system**

Classification Regulation: **21 CFR 892.1680**

Device Class: **Class II**

Product Code (Procode): **MWP**

Panel: **Radiologic Devices Panel**

Premarket Notification submitter:  
Company Name:

**Faxitron Bioptics LLC**

Company Address:

**3440 E. Britannia Dr. Suite 150  
Tucson Az, 85706  
(520) 399-8180**

Contact:

**Paul Hess, Carlos Reyes**

Preparation Date:

November 2015

**A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)**

The **BioVision(Plus) Digital Specimen Radiography (DSR) System** is substantially equivalent to the BioVision Digital Specimen Radiography System, manufactured by Faxitron Bioptics LLC. as a cabinet X-ray system, K091558.

**B. DEVICE DESCRIPTION – as required by 807.92(a)(4)**

The **BioVision(Plus) Digital Specimen Radiography (DSR) System** is a stand-alone cabinet digital X-ray imaging system designed to provide rapid verification that the correct tissue has been excised.

Performing the verification directly in the same procedure room 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.

The **BioVision(Plus) Digital Specimen Radiography (DSR) System** employs the use of **Faxitron Bioptics Vision** image acquisition software. The **Vision** software handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal.

**Faxitron Bionics Vision** software is the central part of this system. The **Vision** software is Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and comes with DICOM Print, Store and Modality Work List (MWL).

**C. DEVICE CLAIMS - as required by 807.92(a)(4)**

The **BioVision(Plus) Digital Specimen Radiography (DSR) System** is of compact and portable design that plugs into any A/C outlet and requires no external X-ray shielding. The **system** offers one-button operation utilizing automatic exposure control for optimal X-ray exposure. This device offers high resolution digital X-ray imaging with small area formats.

The **Vision** software transfers images to Radiology and Pathology within seconds through DICOM interface.

**D. PRODUCT AND TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4)**

The **Faxitron Bionics Vision** software is the central part of this system and handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving and transmittal. The software is Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and comes with DICOM Print, Store and Modality Work List (MWL). The **Vision** software transfers images to Radiology and Pathology within seconds through the DICOM interface.

**Specifications**

Automatic kV Option	Included
Automatic Exposure Time Option	Included
Manual Exposure Time Selection	Included
Geometric Magnification	Included
One-Button Calibration	Included
Energy Range	5-50 kV
Tube Current	1.0 mA max, 12W isopower
X-ray Coverage	28.4 cm
External X-ray shielding	Not required
Imaging Area (mm)	Up to 24cm X 30cm
Resolution (contact mode)	21 lp/mm
Focal Spot	10 um nominal
DICOM Interface (store, print, work list)	Included
Manual kV Selection	Included
Window Filtration	0.2 mm Beryllium

**E. INDICATED USE - as required by 807.92(a)(5)**

The BioVision (Plus/ +) Digital Specimen Radiography (DSR) System is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of harvested specimens from various anatomical regions, and to provide rapid verification that the correct tissue has been excised.

Performing the verification directly in the same biopsy procedure room 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. This device is intended to be operated wherever the medical professionals deem appropriate, including a surgical suite or a room adjacent to a surgical suite.

**F. LEVEL OF CONCERN – as requested by recent FDA guidance**

**Faxitron Bioptics LLC** has determined that the submitted device has a “**moderate**” software **Level of Concern** and has provided that documented record as part of this submission.

**G. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)**

The **BioVision(Plus) Digital Specimen Radiography (DSR) System** has the same indications for use as the BioVision Digital Specimen Radiography (DSR) System, K091558. The **BioVision (Plus) Digital Specimen Radiography (DSR) System** has the same technological characteristics as **the BioVision Digital Specimen Radiography (DSR) System**. Section III Substantial Equivalence of this submission provides a detailed COMPARISON MATRIX of the predicate BioVision Digital Specimen Radiography (DSR) System to the BioVision (Plus) Specimen Radiography (DSR) System.

The submitter claims that the **BioVision(Plus) Digital Specimen Radiography (DSR) System** is substantially equivalent to the predicate device, the BioVision Digital Specimen Radiography (DSR) System.

The technological characteristics of the **BioVision (Plus) Digital Specimen Radiography (DSR) System** are very similar to those of the BioVision Digital Specimen Radiography (DSR) System. The differences include:

TABLE OF DIFFERENCES BETWEEN  
THE BIOVISION (PLUS) AND THE BIOVISION  
DIGITAL SPECIMEN RADIOGRAPHY (DSR) SYSTEMS

<b>Characteristic</b>	<b>BioVision(Plus)</b>	<b>BioVision (Predicate device)</b>
X-ray coverage	28.4 cm	19.0 cm
Typical Imaging area (mm)	Up to 240mm x 300mm	75 x 50, 100 x 150,120 x 180, 180 x 240mm
Film or Digital Imaging	Yes	Yes
Energy Range	5-50 kV	5-45 kV
Resolution (contact mode)	21 lp/mm (24.1 microns)	10 lp/mm (48.2 microns)
Footprint (Overall Dimensions)	53cm w x 38cm d x 170cm h	53cm w x 38cm d x 170cm h
Used for excised and harvested specimens	Yes	Yes

Externally the BioVision and BioVision+ are virtually identical. The only physical difference is the branding label has the "+" and the rear identification label has the product name change.

Internally the physical component changes that affect the function are

<b>Item</b>	<b>BioVision (Plus)</b>	<b>BioVision</b>
X-Ray Source	50kV Microfocus Tube	45kV Tube
X- Ray Power Supply	50kV Microfocus high voltage supply	45kV high voltage supply
X-Ray Detector	21 line pair Faxitron X-Ray Camera (Sensor Modules 343) With Fiberoptic Faceplate and Columnar CsI:TI Phosphor Plate	10 line pair Faxitron X-Ray Camera (Sensor Modules 242) With Fiberoptic Faceplate and Columnar CsI:TI Phosphor Plate
Specimen Magnification	Three chamber shelves for 1.5 2.0 and 3.0 times magnification	Two chamber shelves for 1.5 and 2.0 times magnification

In essence the BioVision(Plus) is a higher resolution version of its equivalent predicate device. It achieves this by using a smaller focal spot on the X-Ray tube (micro focus) to increase image sharpness and higher resolution X-Ray detector. From the users point of view it functions in the exact same way and physically looks identical. The only difference the user will hopefully notice is the improved image quality.

The submitter concludes that the **BioVision(Plus) Digital Specimen Radiography (DSR) System** employs the same type of technological characteristics including X-ray technology, power source, digital imaging, computer interface for user functionality, computer hardware, operating system, and similar functionality to the predicate BioVision Specimen Radiography System. The majority of differences are either not significant or relate to evolutionary changes in technology that have occurred since the release of the BioVision Digital Specimen Radiography (DSR) System.

**H. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)**

As a cabinet or specimen X-ray device, the submitted device is required to comply with Part 1020, FDA's performance standards for ionizing radiation emitting products and specifically to 21 CFR 1020.40 Cabinet X-ray systems. The **BioVision(Plus) Digital Specimen Radiography (DSR) System** conforms to 21 CFR 1020.40. Evidence of the compliance is provided throughout this submission and is referenced in the appropriate exhibits.

The radiation emitted from the **BioVision(Plus) Digital Specimen Radiography (DSR) System** cabinet x-ray system does not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface. Additionally, the submitted device has been designed in a device design and manufacturing environment with an ISO 13485 and 9001 quality system.

Extremely controlled and detailed design inputs and outputs define all of Faxitron Bioptics LLC product development activities. Some of these activities include, but are not limited

to, detailed design specifications, verification and validation activities, and revision history and revision documentation. An emphasis on controlled software activities include risk assessment and management, level of concern and configuration management. These activities are thoroughly documented and reviewed and approved by appropriate authorized authorities.

The submitter believes and claims that the submitted device was developed, designed, tested and validated to perform in a manner that accurately portrays the submitted systems intended use, functionality, safety features, user interface, operation, and documentation. The results of these activities were reviewed by appropriate management and that review resulted in the documented determination that the submitted device met its design plan, is safe and effective, and, subsequent to FDA review of this submission, is ready for commercial distribution as a medical device.

The submitted device's software controls were subjected to significant verification and validation testing. Verification testing was performed during software coding and results were recorded as "comments" in the software code. Alpha validation testing included testing of all functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface or documentation.

Alpha validation activities included specified system software and operating software performance and environmental testing within the specified environment. Additionally, a few devices, labeled "Research Use Only," are being placed to further document the submitter's performance claims and attempt to identify any unknown hazards. Any significant findings will be investigated and resolved appropriately. If a significant finding rises to an appropriate level, the submitter will take appropriate FDA notification action.

The predicate device, BioVision Digital Specimen Radiography (DSR) System did not provide or reference any clinical tests submitted in compliance with **807.92(b)(2)**, therefore the submitter believes such clinical testing is not appropriate or required by FDA and has not made or provided any summary of such testing.

## **I. SUBSTANTIAL EQUIVALENCE SUMMARY**

The BioVision Digital Specimen Radiography (DSR) **System** has the same indications for use as the **BioVision(Plus) Digital Specimen Radiography (DSR) System**. The BioVision Digital Specimen Radiography (DSR) System has the same technological characteristics as the **BioVision(Plus)Digital Specimen Radiography (DSR) System**. However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation and imaging performance test identical to that of predicate device to further document equivalence. This performance data includes

- Spatial resolution tests to ensure the image quality, with a line pair gauge and America College Radiology phantom.
- Contrast resolution tests using a Small Field Low Contrast Phantom.
- Product safety tests meet and exceed the requirements of CDRH 21 CFR 1020.40 and UL 61010-1, 3<sup>rd</sup> Edition for Safety Requirements for Electrical Equipment for measurement, control and laboratory use, including particular requirements for cabinet X-Ray systems.

The results of this testing substantiates that the **BioVision(Plus) Digital Specimen Radiography (DSR) System** performs as well as the predicate, the BioVision Digital Specimen Radiography (DSR) System.

## **J. CONCLUSIONS**

The performance testing and validation studies document that the **BioVision(Plus) Digital Specimen Radiography (DSR) System** is substantially equivalent to the BioVision Digital Specimen Radiography (DSR) System.