K052433

OCT 1 8 2005

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by §807.92

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

Trade Name:	**piXarray 100 Digital Specimen Radiography (DSR) 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**

Premarket Notification submitter:

Company Name:	**Bioptics, Inc.**
Company Address:	**3496 S. Dodge Blvd, Ste 110** **Tucson, AZ 85629-5477**
Contact:	**Jeffrey Orach, V.P. Manufacturing and Regulatory Affairs**
Preparation Date:	September 2, 2005

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

The **piXarray 100 Digital Specimen Radiography (DSR) System** is substantially equivalent to the **Mammopath™** [trade mark of Fischer Imaging Corporation, Denver, Colorado] cabinet X-ray system, **K021113**.

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

The **piXarray 100 Digital Specimen Radiography (DSR) System** is a stand-alone cabinet digital X-ray imaging system to provide rapid verification that the correct tissue has been excised during excisional or percutaneous biopsy.

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.

The **piXarray 100 Digital Specimen Radiography (DSR) System** employs the use of **Biopix** image acquisition software. The **Biopix** software handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal. **Biopix** software is the central part of this system. **Biopix** 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 **piXarray 100 Digital Specimen Radiography (DSR) System** is of compact and portable design plugs into any A/C outlet and requires no external X-ray shielding. The **piXarray 100 DSR System** offers one-button operation utilizing automatic exposure control for optimal X-ray exposure. High resolution digital imaging with large area formats is available. Standard 18cm x 24cm cassette slot is available for film archival.

The **Biopix** software transfers images to Radiology and Pathology within seconds though DICOM interface.

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

The **piXarray 100 Digital Specimen Radiography (DSR) System** is of compact and portable design plugs into any A/C outlet and requires no external X-ray shielding. The **piXarray 100 DSR System** offers one-button operation utilizing automatic exposure control for optimal X-ray exposure. High-resolution digital imaging in large area formats is available.

Available imaging formats are:
50 mm x 50 mm
50 mm x 100 mm
100 mm x 100 mm
Larger area formats are under development and can be made available upon request.

Standard 18cm x 24cm cassette slot for film archival is available.

The **Biopix** software handles the digital X-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal. **Biopix** software is the central part of this system. **Biopix** software is Digital Imaging and Communications in Medicine (DICOM) 3.0 compliant and comes with DICOM Print, Store and Modality Work List

- A device intended to provide rapid verification, through x-ray examination, that the correct tissue has been excised during excisional or percutaneous biopsy.
- A device intended to create an x-ray image of biopsy material, including in the biopsy procedure room or wherever medical professionals deem appropriate, to enable the rapid x-ray examination of the biopsy specimen and the rapid verification that the correct specimen was excised.

F. INDICATIONS FOR USE

The **piXarray 100 Digital Specimen Radiography (DSR) System** is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of various anatomical regions, and to provide rapid verification that the correct tissue has been excised during excisional or percutaneous biopsy.

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.

G. LEVEL OF CONCERN – as requested by recent FDA guidance

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

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

The **piXarray 100 Digital Specimen Radiography (DSR) System** has the same indications for use as the **Mammopath cabinet X-ray system, K021113**. The **piXarray 100 Digital Specimen Radiography (DSR) System** has the same technological characteristics as the **Mammopath cabinet X-ray system**. **Section III Substantial Equivalence** of this submission provides a detailed **COMPARISON MATRIX** of the **piXarray 100 Digital Specimen Radiography (DSR) System** to the predicate **Mammopath cabinet X-ray system**.

The submitter claims that the **piXarray 100 Digital Specimen Radiography (DSR) System** is substantially equivalent to the predicate device, the **Mammopath cabinet X-ray system**.

The technological characteristics of the **piXarray 100 Digital Specimen Radiography (DSR) System** are very similar to those of the **Mammopath cabinet X-ray system**. The differences include:

TABLE OF DIFFERENCES BETWEEN THE piXarray 100 DIGITAL SPECIMEN RADIOGRAPHY (DSR) SYSTEM AND THE MAMMOPATH CABINET X-RAY SYSTEM

Characteristic	Mammopath System	piXarray DSR System
Energy Range	10-35 kV	5-45 kV
Tube Current	0.1 mA	0.5 mA
X-ray Coverage	14.6 cm	19.0 cm
Window Filtration	0.8 mm Beryllium	0.2 mm Beryllium
Footprint (Overall Dimensions)	36cm w x 34cm d x 39cm h	38cm w x 41cm d x 66cm h

The submitter concludes that the **piXarray 100 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 **Mammopath cabinet X-ray system**. The majority of differences are either not significant or relate to evolutionary changes in technology that has occurred since the release of the **Mammopath cabinet X-ray system**.

I. 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 **piXarray 100 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 **piXarray 100 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. See Radiographic Control Certificate, Document # 1240 is included in this exhibit.

Additionally, the submitted device has been designed in a device design and manufacturing environment with a robust quality system.

Extremely controlled and detailed design inputs and outputs define all of Bioptics 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. Refer to "Software Revision History", Document # 1239, included in Exhibit 9.

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.

To the submitter's knowledge, the predicate device, **Mammopath cabinet X-ray 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.

J. SUBSTANTIAL EQUIVALENCE SUMMARY

The **piXarray 100 Digital Specimen Radiography (DSR) System** has the same indications for use as the **Mammopath cabinet X-ray system**. The **piXarray 100 Digital Specimen Radiography (DSR) System** has the same technological characteristics as the **Mammopath cabinet X-ray system**. However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation and performance testing to further document equivalence. The results of this testing substantiates that the

piXarray 100 Digital Specimen Radiography (DSR) System performs as well as the predicate, the **Mammopath cabinet X-ray system**.

K. CONCLUSIONS

The performance testing and validation studies document that the **piXarray 100 Digital Specimen Radiography (DSR) System** is substantially equivalent to the **Mammopath cabinet X-ray system**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2005

Mr. Jeffrey Orach
Vice President Manufacturing
& Regulatory Affairs
Bioptics, Inc.
3496 S. Dodge Blvd., Suite 110
TUCSON AZ 85713

Re: K052433
Trade/Device Name: piXarray 100 Digital Specimen Radiography (DSR) System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: September 2, 2005
Received: September 6, 2005

Dear Mr. Orach:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K052433

Device Name: **piXarray 100 Digital Specimen Radiography (DSR) System**

Indications for Use:

The **piXarray 100 Digital Specimen Radiography (DSR) System** is a cabinet digital X-ray imaging system intended to generate and control X-rays for examination of various anatomical regions, and to provide rapid verification that the correct tissue has been excised during excisional or percutaneous biopsy.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052433