K091928

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

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

Trade Name:	**10 X 10 VISION**
Common/Classification Name:	**Stationary X-Ray System**
Classification Regulation:	**21 CFR §892.1680**
Device Class:	**Class II**
Product Code (Procode):	**90 MWP**
Premarket Notification submitter:	
Company Name:	**Bioptics, Inc.**
Company Address:	**3440 E. Britannia Dr. Suite 150** **Tucson, AZ 85706**
Contact:	Akif Baysal
Preparation Date:	2/21/2009

JUN 1 5 2010

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

The submitted device, **10 X 10 VISION,** is substantially equivalent to the **MammoPath®** [registered trade mark of Fischer Imaging Technologies, Denver, Colorado- Stationary X-Ray System, **K021113.**

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

The **10 X 10 VISION** will be marketed as a digital specimen radiography add-on upgrade for standard film-based cabinet x-ray systems. using high-performance, flat panel CMOS detector, and high-resolution Gd2O2S:Tb (Gadolinium Oxysulfide) scintillator technologies.

Bioptics digital x-ray imagers are packaged in a thin (<14 mm) form factor similar to standard film cassette, include power supply, cables and needed mechanical accessories for convenient and cost-efficient upgrade of existing film-based cabinet x-ray systems. The x-ray imager assembly is installed permanently in the detector/cassette housing compartment or at the base of the host cabinet x-ray unit. The passive x-ray detection technology does not emit radiation and its low power (<5W) consumption does not require additional cooling.

The **10 X 10 VISION** employs the use of **Bioptics Vision** image acquisition software. The **Bioptics Vision** software handles digital x-ray image acquisition, calibration, image display, image analysis and manipulation, patient database, image archiving, and transmittal. Bioptics Vision software is the central part of this system. **Bioptics Vision** software is compliant with Digital Imaging and Communications in Medicine (DICOM) 3.0, and comes with DICOM Print, Store and Modality Work List (MWL).

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

The Gd2O2S(Tb) scintillator and 50 micron pixels provide high sensitivity with high resolution and dynamic range. The ***10 X 10 VISION*** is easy to use, has "easy to learn (intuitive) software controls, is bundled with PCI capture card and image processing software for the host PC. Multiple image area sizes are available from 5 cm x 5 cm to 18cm x 24cm. The imager will be fixed in the base of the host cabinet x-ray unit during

installation, limiting and excluding any other potential uses of 10 x 10 Vision from mammography applications other than specimen radiography.

The ***Bioptics 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 ***10 X 10 VISION*** is a stationary x-ray device for use in 21 CFR 1020.40 compliant cabinet x-ray units as an add-on digital specimen radiography upgrade. The Gd2O2S(Tb) scintillator and 50 micron pixels provide high sensitivity with high resolution and dynamic range. The ***10 X 10 VISION*** allows the user to select automatic exposure techniques, providing for repeatable results. The ***10 X 10 VISION*** is easy to use, has "easy to learn (intuitive) software controls, is bundled with PCI capture card and image processing software for the host PC. Multiple image area sizes are available from 5 cm x 5 cm to 18cm x 24cm.

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

Specifications for ***10 X 10 VISION:***

- DICOM V3.0 standards and protocol structure
- Windows-based Graphical User Interface
- Provides DICOM networking interface
- System calibration required
- User controls number of calibration images
- Calibration images calibrate "raw" x-ray images on a pixel-by-pixel basis to generate a "corrected" image for display
- Software allows for storage of patient information, physician, technologist name and ID, procedure name, position view, study name and ID, accession #, body part, laterality, Institution name and comments
- Software controls complete image acquisition and processing
- Software provides extensive database module
- Software provides User Guide "Help"
- Power 90-240 VAC, 50/60 Hz
- Image Analysis
- Display equipment
- Imaging area: 50 x 50mm- 180 x 240 mm
- Digital Imaging
- Energy Range dependent upon host Mammographic or Cabinet X-Ray System
- Resolution (contact mode): 10 lp/mm (50 microns)
- Magnification with image presentation display tools
- Computer hardware
- Microsoft Computer Operating System
- Computer input/output devices
- User aids manual with troubleshooting
- Minimum Image Display Time 4 seconds

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

Bioptics defines intended use as the objective intent of the manufacturer or person(s) legally responsible for the labeling of devices and includes labeling claims, advertising matter, and approved oral or written statements by such firms or their representatives. As such, Bioptics intends its advertising matter, specifications, user manual and other written or authorized oral statements to identify the objective intent of Bioptics.

Bioptics intends that the submitted device's intended uses include and limited to the following:

- digital specimen radiography with 21 CFR 1020.40 compliant ,shielded x-ray cabinets

The ***10 X 10 VISION*** will be used by trained medical and technical staff in an appropriate medical facility or clinic environment.

F. INDICATIONS FOR USE

The Bioptics 10 X 10 VISION is a digital upgrade to previously released 21 CFR 1020.40 compliant cabinet x-ray systems. The 10 X 10 Vision is used for digital specimen radiography to provide rapid verification that the correct tissue has been excised during excisional or percutaneous biopsy. The 10 X 10 Vision is excluded from any use in in-vivo diagnostic or screening mammography applications.

G. LEVEL OF CONCERN

The FDA guidance document "***Guidance For The Content of Premarket Submissions For Software Contained In Medical Devices***," May 11, 2005, clearly identifies the manufacturer's responsibility to assess each submission and determine the Level of Concern for that submitted device. Bioptics, Inc. intends to document that assessment in EXHIBIT 4.

Bioptics, Inc. acknowledges and documents that responsibility and **Bioptics**' assessment of the submitted device, based on its indications for use and design, is that the submitted device has a **MODERATE Level of Concern.**

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

The ***10 X 10 VISION*** has the same indications for use as the Fischer MammoPath Stationary X-ray System System (K021113). The ***10 X 10 VISION*** has the same technological characteristics as the Fischer® MammoPath Stationary X-Ray System Section III Substantial Equivalence of this submission provides a detailed comparison matrix of the ***10 X 10 VISION*** to the predicate device.

The submitter claims that the ***10 X 10 VISION*** is substantially equivalent o the predicate device, the Fischer® MammoPath Stationary X-ray System.

The submitter concludes that the ***10 X 10 VISION*** employs the same type of technological characteristics including digital imaging, computer interface for user functionality, computer hardware, operating system, and similar functionality to the Fischer MammoPath Stationary X-ray System.

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

As an accessory component of a diagnostic X-ray device that requires a) an initial determination of compatibility with the system and b) which may be interchanged with similar compatible components without affecting the system's compliance, the submitted device is required to comply with Part 1020, FDA's performance standards for ionizing radiation emitting products.

Specifically, compliance to 21 CFR 1020.30 Diagnostic x-ray systems and their major components is required. Additionally, Bioptics, inc. has validated that use of our ***10 X 10 VISION*** will not affect compliance with the requirements set forth in 21CFR 1020.31 upon installation into standard 21 CFR 1020.40 compliant Cabinet X-ray Systems by performing tests to assure that radiation emissions, leakage current are in compliance.

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 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 has undergone significant verification and validation testing. Software validation testing included testing of all executable code and functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface, documentation or user SOP.

Software validation activities included comprehensive validation scripts of all Software Design Specifications (SDS), which is summarized and discussed in the EXHIBITS to provide a preliminary record of performance data. Additionally, the submitter duplicated the operational environment of a sophisticated user and provided the complete record of those executed scripts as operational performance data in the EXHIBITS. The output of these two performance data records documents that ***10 X 10 VISION*** met its required requirements and design specifications as intended.

Additionally, a device labeled "For Investigational Use Only" is 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 rises to an appropriate level, the submitter will take appropriate FDA notification action.

To the submitters knowledge, the predicate device, Fischer MammoPath Stationary 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 ***10 X 10 VISION*** has the same indications for use as the Fischer MammoPath Stationary X-Ray System (K021113). The ***10 X 10 VISION*** has the same technological characteristics as the predicate device. 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 substantial equivalence. The results of this testing substantiates that ***10 X 10 VISION*** performs as well as the predicate devices.

K. CONCLUSIONS

The performance testing and validation studies document that ***10 X 10 VISION*** is substantially equivalent to the predicate device Fischer MammoPath Stationary X-Ray system (K021113)

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

JUN 1 3 2010

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V.P. of Research and Development
Bioptics, Inc.
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TUCSON AZ 85743

Re: K091928
Trade/Device Name: 10 X 10 VISION
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: June 11, 2010
Received: June 14, 2010

Dear Dr. Baysal:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K091928

STATEMENT OF INDICATIONS FOR USE

Device Name: **10 X 10 VISION**

Indications for Use:

The Bioptics 10 X 10 VISION is a digital specimen radiography add-on upgrade to previously released cabinet x-ray systems. The 10 X 10 Vision is used for digital specimen radiography to provide rapid verification that the correct tissue has been excised during excisional or percutaneous biopsy. The 10 X 10 Vision is excluded from any use in in-vivo diagnostic or screening mammography applications.

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K091928