



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

Focal Healthcare, Inc.  
% Mr. Georg Bauer  
510(k) TPR Deputy Program Manager  
TUV SUD America, Inc.  
1775 Old Highway 8 NW  
NEW BRIGHTON MN 55112-1891

January 25, 2016

Re: K153166  
Trade/Device Name: Fusion Bx  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: December 14, 2015  
Received: January 11, 2016

Dear Mr. Bauer:

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 over a large, faint, grey watermark of the FDA logo.

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)

K153166

Device Name  
Fusion Bx

Indications for Use (Describe)

Fusion Bx is intended for use by physicians for enhanced visualization of ultrasound imaging of the prostate in clinic and hospital settings. It provides 2D and 3D image visualization including review, manipulation, and analysis tools. Additional features include patient data management, image measurement, multiplanar reconstruction, 3D image registration, segmentation, image annotation, and to record the locations where the biopsies were acquired during the procedure.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

[As required by 21 CFR 807.92]

Submitter's Name: Focal Healthcare Inc.  
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Date Prepared: 21 August 2015

Device Proprietary Name: Fusion Bx™  
Device Common or Usual Name: Medical Image Processing Workstation  
Classification Name: System, Image Processing, Radiological  
Product Code: LLZ  
Regulation Number: 21 CFR 892.2050  
Regulation Description: Picture Archiving and Communications System

### Predicate Device:

Substantial equivalence is claimed to the following device:

<b>Name of Device</b>	3-D Imaging Workstation
<b>Manufacturer</b>	Eigen LLC
<b>510(k) Number</b>	K081093

### Device Description and Summary of Technological Characteristics

Fusion Bx is designed to display the 2D live video received from commercially available ultrasound machines and use this 2D video to reconstruct a 3D ultrasound image volume. The system is designed to work with clinicians' existing ultrasound machines, transrectal ultrasound (TRUS) probes, commercially available needles, needle guides/templates and needle gun combination. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurements and 3D image registration. The device will assist clinicians in planning and performing image-guided interventional procedures such as biopsies and placing instruments in the prostate for adult men with suspected prostate cancer.

Fusion Bx is comprised of a laptop-based workstation and a hardware assembly. The included hardware consists of a frame grabber, encoder converter, hardware arm (comprising of a swing arm, counterbalance, tracker and stepper), and stand. The stepper holds the ultrasound probe and measures probe position while the physician performs a normal ultrasound imaging

procedure of the subject prostate. Encoders in the stepper and tracker send joint movement information to the computer workstation which tracks probe position and orientation. Control of the ultrasound probe and ultrasound system is done manually by the physician, just as it would be in the absence of Fusion Bx. However, by tracking the position and orientation of the ultrasound probe while capturing the video image, the workstation is able to reconstruct and display a 3D image and 3D rendered surface model of the prostate and to display the live image position within the prostate.

The computer workstation is connected to the ultrasound system via a cable and hardware device that converts the real-time video stream 2D ultrasound image into a format that is readable by Fusion Bx. The reconstructed 3D image stack can be marked up with gland segmentation or other markers. Previously-acquired images of the patient's prostate can be registered to this 3D stack, based on the principle that features of the prostate can be visualized consistently with a number of imaging modalities.

The physician may attach a commercially available biopsy needle guide to the TRUS probe and use the probe and biopsy needle to perform the prostate biopsy procedure. During the biopsy procedure this real-time 2D ultrasound image is always visible on the Fusion Bx display. This 2D live ultrasound image can be marked up to record the locations where the biopsies were acquired during the procedure. As the probe and needle guide are maneuvered by the physician, the position and orientation of the probe is tracked. Needle trajectory is estimated by Fusion Bx and can be shown relative to the 3D image stack. This information is provided so the physician can assess prostate abnormalities, plan and implement biopsy procedures.

Supported imaging modalities include DICOM images and real-time 2D ultrasound images. DICOM-compliant images are received through CD, USB memory stick, or over a network connection. Images that are compressed will not be processed. This includes images that have been compressed using lossy, such as JPEG, and lossless, such as JPEG2000, compression methods. The 3D images can be further processed to perform volume estimations of the prostate segmentation and/or regions of interest (ROIs). Length measurements are also available.

Data, notes and images are stored in the patient file for later retrieval. Images are stored as unchanged originals. Image mark-ups are stored in DICOM format with the same image size and orientation as the 3D ultrasound stack. Measures are in place to protect against data loss. This includes file transfer where data loss is evaluated upon receipt and/or reading of data.

In summary, Fusion Bx offers the physician additional 3D information for assessing prostate abnormalities, planning and implementing biopsy procedures. The additional image processing features are generated with minimal changes to previous TRUS probe-based procedures, and the physician always has access to the live 2D ultrasound image during prostate assessment or biopsy procedure. The system will integrate into existing workflow by connecting to standard ultrasound equipment. This system will not prevent the clinician from using the standard ultrasound equipment.

### Intended Use/Indications for Use

Fusion Bx is intended for use by physicians for enhanced visualization of ultrasound imaging of the prostate in clinic and hospital settings. It provides 2D and 3D image visualization including review, manipulation, and analysis tools. Additional features include patient data management, image measurement, multiplanar reconstruction, 3D image registration, segmentation, image annotation, and recording of the locations where the biopsies were acquired during the procedure.

### Substantial Equivalence

The product's technical features are substantially equivalent to the Eigen 3-D Imaging Workstation (K081093). Both are software applications that provide 2D and 3D medical image viewing and acquisition to aid visualization of the prostate gland. Both devices provide additional features which include patient data management, multi-planar reconstruction, prostate segmentation, image measurement and annotation, 3D surface/image registration, and recording the locations where biopsies were acquired during a procedure. In addition, both devices are composed of a mechanical assembly, and a computer-based workstation. The mechanical assembly holds the ultrasound probe and tracks probe position while the physician performs a normal ultrasound imaging procedure of the subject's prostate. Ultrasound system operation and transrectal probe movement all remain under manual control of the physician.

The differences between the two devices can be characterized as the minor addition or removal of features that have no impact on the overall safety or workflow of the device. These include:

- Minor differences in the mechanical assembly designed to achieve the same purpose, i.e. to track the position and orientation of the ultrasound probe while capturing the ultrasound video image.
- Pay-per-use functionality of the Fusion Bx system.
- Fusion Bx does not allow recording of video sequences.
- The predicate device only supports an end-fire probe, whereas Fusion Bx supports both a side-fire probe and a bi-plane probe (side- and end-fire). The reconstruction requires the probe to be in the side-fire mode, while biopsy navigation supports both side-fire and end-fire modes of operation.

These differences do not raise any safety or effectiveness concerns.

### Testing and Performance Data

The Fusion Bx has been designed to comply with the following standards:

- ISO 14971: 2007 [2012]
- IEC 62304: 2006
- AAMI/ANSI ES 60601-1: 2005/(R)2005 + A1: 2012 (E)
- IEC 60601-1-2: Edition 3: 2007
- IEC 62366-1: Edition 1.0: 2015
- NEMA PS 3.1 - 3.20: 2011 - Digital Imaging and Communications in Medicine (DICOM)

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were used to verify system performance through verification, validation and benchmarking. Compatibility with the BK ultrasound and the 8088 and 8188 probes was confirmed. Through careful measurements, the measured error in the positioning system was determined to be acceptable at less than 2.5 mm and less than 0.176° at the tip of the probe, and the geometric error in the ultrasound reconstruction was determined to be acceptable at less than 3% volume difference and less than a 2.5 mm error in distance measurements.

**Conclusion**

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of Fusion Bx with those of the predicate device demonstrate that Fusion Bx is substantially equivalent to the existing product in the market today.

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