Focal Healthcare Inc.
℅ Karen Zhou, JD, MS
Senior Associate, Regulatory Affairs & Quality
10 Morrow Ave., Unit 101
Toronto, Ontario M6R 2J1
CANADA

June 15th, 2018

Re: K181290
Trade/Device Name: Fusion Bx 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 11, 2018
Received: May 31, 2018

Dear Ms. Zhou:

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.

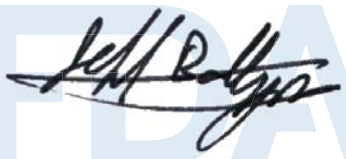
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181290

Device Name
Fusion Bx 2.0

Indications for Use *(Describe)*
Fusion Bx 2.0 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.
Submitter's Address:	10 Morrow Avenue, Suite 101 Toronto, ON M6R 2J1 Canada
Contact Name:	Ms. Karen Zhou, JD, MS
Title:	Senior Associate, Regulatory Affairs & Quality
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Date Prepared:	11 May 2018
Device Proprietary Name:	Fusion Bx™ 2.0
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:

Device Proprietary Name:	Fusion Bx™
Manufacturer	Focal Healthcare Inc.
510(k) Number	K153166
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

Device Description and Summary of Technological Characteristics

Fusion Bx 2.0 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.

Fusion Bx 2.0 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.

Intended Use/Indications for Use

The indications for use statement for Fusion Bx 2.0 is identical to the predicate device.

Indications for Use Statement:

> Fusion Bx 2.0 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.

This device will assist clinicians in planning and performing image-guided interventional procedures such as biopsies and placing instruments and markers in the prostate. The device is intended for adult men with suspected prostate disorders such as cancer or other prostate problems.

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.

Substantial Equivalence

Fusion Bx 2.0 has the same device description and intended use compared to the predicate device also manufactured by Focal Healthcare Inc. The difference includes software and minor hardware updates:

- Hardware
  - Hardware improvements for ease of use, ergonomics and aesthetics
- Software
  - Code refactoring for more robust performance
  - Bug fixes

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
- IEC 60601-1: 2005 + A1: 2012 (E)
- IEC 60601-1-2: 2007/2012
- IEC 62366: 2008
- NEMA PS 3.1 - 3.20: 2011 - Digital Imaging and Communications in Medicine (DICOM)

Fusion Bx 2.0 was test according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (published on May 11, 2005) and Content of Premarket

Submission for Management of Cybersecurity in Medical Devices (published on October 2, 2014). Verification and validation plans and reports are provided as a part of the submission to demonstrate substantial equivalence to the predicate device.

Conclusion

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of Fusion Bx 2.0 with those of the predicate device demonstrate that Fusion Bx 2.0 is substantially equivalent to the predicate device.

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