DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Biobot Surgical Pte Ltd
% Ms. Lai Chee Liew
Head of Quality, Regulatory Affairs
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#03-10 Woodlands Sector 1
SINGAPORE 738068

October 6, 2016

Re: K161109
Trade/Device Name: iSR'obot MRI-US Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 25, 2016
Received: September 8, 2016

Dear Ms. Liew:

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,

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K161109

Device Name

iSR'obot MRI-US Fusion

Indications for Use *(Describe)*

The iSR'obot MRI-US Fusion is a software application to be used by Clinicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of Magnetic Resonance and Ultrasound images for mapping planning information of the prostate gland and region of interest. The software features also include multi-modality data communication, surface and volume rendering, segmentation, multi-planar reconstruction, organ delineation, region of interest delineation, landmark selection, measurements and data reporting.

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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# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date: August 24, 2016

Submitter: Biobot Surgical Pte Ltd
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## Product Identification

Device Trade Name: iSR'obot MRI-US Fusion

Common / Usual Name: Picture Archiving and Communication System

Classification Names: 21 CFR 892.2050, System, Image Processing, Radiological

Product Code: LLZ

Manufacturer / Design Location: Biobot Surgical Pte Ltd
2 Woodlands Spectrum I, #03-10 Woodlands Sector 1,
Singapore 738068

Manufacturing Location(s): Biobot Surgical Pte Ltd
2 Woodlands Spectrum I, #03-10 Woodlands Sector 1,
Singapore 738068

Distributor: Biobot Surgical Pte Ltd
2 Woodlands Spectrum I, #03-10 Woodlands Sector 1,
Singapore 738068

## Device Description

The iSR'obot MRI-US Fusion (UroFusion) is a software application intended for use by Clinicians or Radiologist for 2-D and 3-D visualization, image registration and fusion of Magnetic Resonance and Ultrasound images for mapping planning of the prostate gland and region of interest, such as lesions, to provide "MRI-3D model" image information. The "MRI-3D model" image information produced by this software acts as inputs to the iSR'obot Mona Lisa which allows the import of this "MRI-3D model" image information; and fusion of this model information together with the live ultrasound 3D-model image information.

Leveraging on the information available from both Magnetic Resonance (MRI) & Ultrasound modalities concurrently, the fusion results enable the clinicians to visualize the prostate and the region of interest (lesions); thus enabling fewer and more accurate targeted prostate biopsies to be taken as compared with "blind" saturated biopsies with ultrasound guidance alone.

UroFusion software system includes the following features:

- Access and display medical imaging studies from MRI DICOM data.
- Provide for 2D contouring /3D modelling of the prostate gland.
- Provide for 2D contouring / 3D modelling of tumour / lesions within the gland.
- Provide for saving of patient "MRI-3D model" information together with the patient's MRI DICOM data.
- Provide for importing of patient "MRI-3D model" information together with relevant MRI DICOM data.
- Provide for the fusion of "MRI-3D model" information with the live ultrasound 3D- model information for subsequent operations to be executed in iSR'obot Mona Lisa.

UroFusion can be deployed and utilized in commercially available computer platforms and operating systems; or as a standalone system.

The system does not produce any original medical images. All images located on the UroFusion system have been received from DICOM compliant modalities and/or image acquisition systems.

The system allows trained professionals to access and display DICOM images for the purpose of modelling and planning clinical procedures. These trained professionals includes radiologists, urologists, radiology oncologists and interventional oncologists.

**Hardware Description**

The UroFusion is a software-only device that runs on off-the-shelf computer systems. The hardware platform that the device runs on is as follows:

| Hardware Platform | CPU Type | CPU Frequency | Disk Space | Memory | Others |
|---|---|---|---|---|---|
| Desktop or Laptop Computers | 32-bit or 64-bit | 1 GHz and above | ≥ 15 GB Hard disk space | ≥ 8 GB | USB 2.0 interface or CD/DVD Rom |

The components external to UroFusion software are:

| | |
|---|---|
| Mona Lisa Ultrasound Scanning & Modelling | This module is part of the iSR'obot Mona Lisa system that will provide the ultrasound information needed to generate the US-3D model information |
| Mona Lisa Biopsy Planning | This module is part of Mona Lisa system that will provide for planning and execution of prostate biopsies |

The UroFusion is designed and verified to work with iSR'obot Mona Lisa (K130944).

## Intended Use

The iSR'obot MRI-US Fusion is a software application to be used by Clinicians in the clinic or hospital for 2-D and 3-D visualisation, image registration, and fusion of Magnetic Resonance and Ultrasound images for mapping planning information of the prostate gland and region of interest.

## Indications for Use

The iSR'obot MRI-US Fusion is a software application to be used by Clinicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of Magnetic Resonance and Ultrasound images for mapping planning information of the prostate gland and region of interest. The software features also include multi-modality data communication, surface and volume rendering, segmentation, multi-planar reconstruction, organ delineation, region of interest delineation, landmark selection, measurements and data reporting.

## Technology

UroFusion employs the same fundamental scientific technology as that of its predicate device, Multi-modality Image Fusion (K120187). The majority of the software features and functions are common between the two products.

The table below outlines the major subsystem differences and similarities.

| | **Predicate Device: Multi-modality Image Fusion** | **Proposed Device: iSR'obot MRI-US Fusion** | **Discussion of Similarities** |
|---|---|---|---|
| Manufacturer | **Eigen** | **Biobot** | |
| 510(k) number | **K120187** | **Pending** | |
| Where Used | Office settings in clinic or hospital | Office settings in clinic or hospital | **Same** |
| Software Device | Yes | Yes | **Same** |
| Image Registration | Multi-modality image registration | Multi-modality image registration | **Same** |
| System composition | Offline software and online software | Offline software and online software | **Same** |

| | Predicate Device: Multi-modality Image Fusion | Proposed Device: iSR'obot MRI-US Fusion | Discussion of Similarities |
|---|---|---|---|
| Workflow | User first uses offline software to import MRI/CT DICOM data to prepare prostate contours and mark area of interest. Then user uses online software to fuse prepare MRI/CT images to Ultrasound images. | User first uses offline software to import MRI DICOM data to prepare prostate contours and mark area of interest. Then user uses online software to fuse prepare MRI images to Ultrasound images. | **Same** |
| Data Acquisition | DICOM import for MRI images for offline software; snapshot of Ultrasound images for offline software. | DICOM import for MRI images for offline software; snapshot of Ultrasound images for offline software. | **Same** |
| Image Fusion/Overlay Display | Fused overlay of images from multiple modalities | Fused overlay of images from multiple modalities | **Same** |
| Opacity Control | Yes | Yes | **Same** |
| 3-D Rendering | Yes | Yes | **Same** |
| Surface Rendering | Yes | Yes | **Same** |
| Region of Interest | Yes | Yes | **Same** |
| Configurable Image Layouts | Yes | Yes | **Same.** User can choose to see different slice of image stack in any view of the transversal, sagittal and coronal views. |

| | Predicate Device: Multi-modality Image Fusion | Proposed Device: iSR'obot MRI-US Fusion | Discussion of Similarities |
|---|---|---|---|
| 3-D Contours for Planning | Yes | Yes | **Same.** User can define 3-D contours of prostate and area of interest, which can be used for biopsy planning. |
| Export of 3D contours for planning | Yes | Yes | Same. |
| Image Storage and Communication | Yes | Yes | Same. |
| Modalities | CT, MR, Ultrasound | MRI, Ultrasound | This device is tested for MRI and Ultrasound modalities.<br><br>This difference did not raise new safety and effectiveness concerns. |
| Image Construction | Full 3-D image construction from image slices. | Full 3-D image construction from image slices. | **Same** |

**Determination of Substantial Equivalence**

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".
UroFusion complies with voluntary standards as detailed in this premarket notification submission. It also successfully completed all testing per our quality system and it was designed and manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Usability Analysis
- Testing on unit level (Verification)
- Integration testing (Verification)
- Performance testing (Verification)
- Regression testing (Verification)
- System testing (Verification)
- Simulated use testing (Validation)

Biobot believes UroFusion is of comparable type and substantially equivalent to the predicate device based on the table above (Page 5-5 to 5-7) which compares its technology similarities. Both devices' indication for use is similar except the imaging modalities to be used.

| | **Predicate Device: Multi-Modality Image Fusion - K120187** | **Proposed Device: MRI- US Fusion Software** | **Discussion** |
|---|---|---|---|
| Intended Use | The software is intended for 2-D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities. | The iSR'obot MRI-US Fusion is a software application to be used by Clinicians in the clinic or hospital for 2-D and 3-D visualisation, image registration, and fusion of Magnetic Resonance and Ultrasound images for mapping planning information of the prostate gland and region of interest. | **Same** |

| | Predicate Device: Multi-Modality Image Fusion - K120187 | Proposed Device: MRI- US Fusion Software | Discussion |
|---|---|---|---|
| Indications for Use | Multi-Modality Image Fusion is a software application to be used by physicians in the clinic or hospital for 2- D and 3-D visualization, image registration, and fusion of MRI, CT and Ultrasound imaging modalities for mapping planning information across modalities. Additional software features include database management, data communication, surface rendering, segmentation, regions of interest (ROI) delineation, volumetric measurements, and data reporting. | The iSR'obot MRI-US Fusion is a software application to be used by Clinicians in the clinic or hospital for 2-D and 3-D visualization, image registration, and fusion of Magnetic Resonance and Ultrasound images for mapping planning information of the prostate gland and region of interest. The software features also include multi-modality data communication, surface and volume rendering, segmentation, multi-planar reconstruction, organ delineation, region of interest delineation, landmark selection, measurements and data reporting. | Substantially Equivalent<br><br>The indication for use of the MRI-US Fusion Software system is substantially equivalent to the predicate device's indication for use. The ROI information is mapped to Ultrasound modality. |

Therefore, we believe that UroFusion is of comparable type and substantially equivalent to the currently marketed system Multi-modality Image Fusion.

### Summary of Additional Testing

In addition to verification and validation activities successfully completed as required by Biobot's quality system, additional engineering (non-clinical testing) and clinical testing (through literature review) was performed to substantiate performance claims, the indications, and ultimately substantial equivalence.

#### Non-Clinical Testing

The performance evaluation testing used 2 phantoms, measurement of Hausdorff distance and statistical analysis to demonstrate that UroFusion performance was successfully verified and substantiated.

### Clinical Testing

The clinical evaluation of UroFusion was carried out using the literature search route as the intended use and use principle of UroFusion are essentially the same as the other 3D image-processing products already in the market. These products are applied in clinical practice for several years with published data.

The search resulted in 6 relevant papers and 2 statements which were evaluated in regard to the significance and relevance concerning the characteristics of MRI-US Fusion and its clinical application. 3 of them were original clinical studies and the other 3 were review papers that comprehensively cover the publications, relevant devices and application in the market and academic area. The 2 statements were made by physicians who had experiences with our devices.

After evaluation, it is clear that overall operating principle of UroFusion is the same or very similar as those commercial products in the market. When such modelling software is not available, the urologist can only do systematic, random or blind sampling of prostate compared to having a fused MRI-ultrasound model where the urologist can execute biopsy on the planned biopsy sites.

There were also no adverse complications noted in the 6 papers.

In conclusion, given the prior clearances of similar image processing products, extensive global clinical use of MRI-ultrasound coupling, completed verification testing and engineering bench testing that have not raised new questions of safety or effectiveness, the clinical evaluation done for UroFusion is sufficient and no clinical trials are required.

### Substantial Equivalence Conclusion

Comparison of the intended uses, the technological characteristics, and performance specifications demonstrates the functional equivalence of UroFusion to the predicate device, Multi-Modality Image Fusion (K120187). In addition, based on conformance to standards, development under our quality system, and the engineering and clinical testing provided, Biobot believes that the UroFusion is safe and effective, and performs in a substantially equivalent manner to the predicate device.