Biobot Surgical Pte Ltd
℅ Lim Yan Shin
Regulatory Affairs
79 Ayer Rajah Crescent, #04-05
Singapore, Singapore 139955
SINGAPORE

December 22, 2021

Re: K213411
Trade/Device Name: iSR'obot Mona Lisa 2.0
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, LLZ, OIJ
Dated: October 15, 2021
Received: October 19, 2021

Dear Lim Yan Shin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K213411

Device Name
iSR'obot Mona Lisa 2.0

Indications for Use *(Describe)*

iSR'obot Mona Lisa 2.0 is a user-controlled, stereotaxic accessory intended to guide physicians in the planning and positioning of insertion tools, such as a third-party needle or a probe, during image-guided diagnostic and interventional procedures in conjunction with the guidance of transrectal ultrasound involving the prostate gland in a clinical setting. Examples of such procedures include, but are not limited to, image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, and soft tissue ablations.

The iSR'obot Mona Lisa 2.0 provides 2D and 3D visualization of Ultrasound images and the ability to fuse and register these images with those from other imaging modalities such as Magnetic Resonance, etc. It also provides the ability to display a simulated image of an insertion tool on a computer monitor screen, the target organ, and the current and projected future path of the insertion tool taking into account patient movement. Other software features include multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, and 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.

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:	October 15, 2021
Submitter:	Biobot Surgical Pte Ltd 79 Ayer Rajah Crescent, #04-05, Singapore 139955
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Product Identification

Device Trade Name:	iSR'obot Mona Lisa 2.0
Common / Usual Name:	System, image processing, radiological
Classification Names:	892.1560 Ultrasonic pulsed echo imaging system 892.1570 Diagnostic ultrasonic transducer
Product Code:	IYO, ITX, LLZ, OIJ
Manufacturer / Design Location:	Biobot Surgical Pte Ltd 79 Ayer Rajah Crescent, #04-05, Singapore 139955

Device Description

The iSR'obot Mona Lisa 2.0 is user-controlled, stereotaxic accessory intended to guide physicians in the planning and positioning of insertion tools, such as a needle or a probe, during image-guided diagnostic and interventional procedures involving the prostate gland in a clinical setting. The device displays the 2D live image feeds from commercially available ultrasound systems and constructs 3D ultrasound image stacks. The system allows the importation of an MRI image to create a model of patient prostate by providing fusion between Ultrasound and Magnetic Resonance Imaging (MRI). The system is compatible with commercially available ultrasound systems, transrectal ultrasound bi-

plane probes, and commercially available needle devices. Other software features include multi-planar reconstruction, segmentation, image measurements and 2D/3D image registration.

Workstation

The workstation is connected to the ultrasound system via a standard cable and hardware connector and displays the 2D live image feed in a format that is compatible with the iSR'obot Mona Lisa 2.0. Using the application software, the urologist or physician defines the apex and base limits of the prostate gland and the robotic arm moves the ultrasound probe within those limits to capture multiple 2D slices of the prostate gland to construct the 3D image stack. The urologist or physician may refine the constructed 3D image stack by indicating and confirming the planned lesion core or tumor location, anatomical markers within or around the prostate gland, and the prostate gland contour. In addition, the application software can utilize previously acquired images of the patient's prostate, which may include other image modalities like magnetic resonance images and register to this 3D image stack. The completed procedure information can be stored on a location selected by the urologist or physician, such as in the workstation or in a PACS server. The stored procedure information can be used for future review with the patient or examination. Previously stored biopsy procedural plan can be recalled and its 3D model may be aligned and registered to current 3D model of the prostate to facilitate planning of the interventional procedure.

Robotic Navigation Module

The robotic navigation module comprises of a robotic arm and bed rail stabilizer. The stabilizer is a mechanical device and is able to lock and release to position the robotic arm. One end of the stabilizer is first attached to the bed rail while the other end is used to mount the robotic arm so that the robotic arm is able to be positioned close to the patient's perineum while the patient is in a lithotomy position. The robotic arm is a motorized mechanical structure and has two key functions, which is to hold and move the ultrasound probe of a commercially available ultrasound system to display 2D live ultrasound image feeds and to orientate its needle guidance mechanism to facilitate insertion of a commercially available needle (based on a planned and simulated needle trajectory) by the urologist or physician. The movement of the ultrasound probe and the needle guidance mechanism is motorized. As a result, the workstation is able to construct and display a 3D image stack and rendered surface model of the prostate.

During the procedure, the real time 2D ultrasound image is visible on the iSR'obot Mona Lisa 2.0 display. After the robotic arm has orientated its trajectory according to the planned location, the urologist or physician manually inserts the needle into the prostate via the needle guidance mechanism. The 2D live ultrasound image may be marked up to record the actual locations where the needle has been inserted. The system is able to pivot and facilitate re-insertion of the needle if the marked up actual location is distant from the planned location. The urologist or physician is able to observe prostate shift on live ultrasound image, re-register the prostate model and needle location plan to the live ultrasound prostate image.

Needle Guide Holder

The needle guide holder is designed to be used with the iSR'obot Mona Lisa 2.0. It is a component installed on the robotic arm functioning as a channel for insertion tools to go through. The robotic arm has a motorized mechanism to close and open the needle guide holder in order to hold and release the insertion tools. The needle guide holder may be manufactured to fit insertion tools with varying diameters.

Disposables

The iSR'obot Kit is intended to be used with the iSR'obot Mona Lisa 2.0 as a component of a system for performing transperineal prostate procedure. The kit consists of probe sheath, drape and biopsy papers. The probe sheath functions as a sheath to a third-party ultrasound probe for ultrasound scanning of the prostate organ.

Predicate Device Information and Comparison

Predicate Device Name	Predicate 510(k) Submission Reference
iSR'obot Mona Lisa 1.0	K203659 (Primary)
iSR'obot MRI-US Fusion	K161109 (Reference)
iSR'obot Biopsy Kit	K163502 (Reference)
Artemis	K162474 (Reference)

Intended Use / Indications for Use

iSR'obot Mona Lisa 2.0 is a user-controlled, stereotaxic accessory intended to guide physicians in the planning and positioning of insertion tools, such as a third-party needle or a probe, during image-guided diagnostic and interventional procedures in conjunction with the guidance of transrectal ultrasound involving the prostate gland in a clinical setting.

Examples of such procedures include, but are not limited to, image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, and soft tissue ablations.

The iSR'obot Mona Lisa 2.0 provides 2D and 3D visualization of Ultrasound images and the ability to fuse and register these images with those from other imaging modalities such as Magnetic Resonance, etc. It also provides the ability to display a simulated image of an insertion tool on a computer monitor screen, the target organ, and the current and projected future path of the insertion tool taking into account patient movement. Other software features include multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, and reporting.

Technology Characteristics Compared to Predicate Devices

iSR'obot Mona Lisa 2.0 employs the same fundamental scientific technology (design, function and specifications) as that of its legally marketed predicate device, iSR'obot Mona Lisa 1.0 (K203659).

Similarities in technology characteristics include:

- Platform-hosted motorized devices and are able to provide 2D and 3D views of the prostate gland;
- Use the same technology to acquire a transrectal ultrasound image to plan and guide a needle for diagnostic procedure;
- Control the trajectory and depth for needle placement via needle guiding mechanism;
- Fusion of Magnetic Resonance and Ultrasound images for mapping planning information of the prostate gland
- Re-positioning of subsequent needle insertion for the same target lesion after the user has indicated the actual needle landing position from the prior insertion.

Modifications to iSR'obot Mona Lisa 2.0 include:

- The iSR'obot Mona Lisa 2.0 is intended for image-guided diagnostic and interventional procedures while the legally marketed predicate device is intended only for image-guided diagnostic procedure;
- Visualization of simulated images in an interventional procedure of 1) the lesions and their margins and 2) treatment zone;
- Needle guide holder, which acts as a channel for insertion tool positioning, is detachable and can be cleaned and sterilized for subsequent use, and enables multi-needle insertion trajectory planning for interventional procedures;

- Patient movement adjustment function for re-alignment of the prostate model with the live-ultrasound image in the event that prostate shifts due to patient movement during a procedure;
- Connectivity to picture archiving and communication system (PACS) to download DICOM images and download/upload of procedure case; and
- Provide an offline post-procedure review

Other changes include minor user interface variations such as graphics user interface (GUI) design. These differences do not significantly affect the function or use of the device, nor do they raise new or additional safety risks.

These changes are being implemented as a product improvement effort and not due to a corrective action or field action.

iSR'obot Mona Lisa 2.0 has the following technological characteristics, similar to the Artemis (K162474):

- Same intended use for insertion tool planning and navigation for ultrasound image-guided prostate diagnostic and interventional procedures.
- Connecting to standard ultrasound system to display and acquire 2D live ultrasound images of the prostate gland
- Perform other viewing and imaging-processing function such as image segmentation, image multi planar reconstruction, image overlays, and measurements
- Image registration and elastic fusion of ultrasound image with previously created MRI prostate model and/or prior biopsy plan on application software
- Generate 2D/3D model of a prostate model and trajectory of insertion tools
- Plan insertion tool positions on the fused prostate model by physicians and mark the actual position of insertion tools
- Connectivity to PACS to download DICOM images and download/upload of procedure case
- Artemis has a needle guide mechanism attachment similar to the iSR'obot Mona Lisa 2.0, which allows insertion of third-party insertion tools

The differences between iSR'obot Mona Lisa 2.0 and Artemis (K162474) are that:

- **Anatomical Access -** iSR'obot Mona Lisa 2.0 is intended for insertion tools positioned transperineally while Artemis is intended for insertion tools positioned transperineally and transrectally procedure.

- **Positioning of insertion tools** - iSR'obot Mona Lisa 2.0 has an 8 axis motorized robotic arm that navigates the needle guide holder based on the clinician's insertion tool position plan. The Artemis has a semi-robotic arm (mechanical arm with encoders) that clinicians may control to track and visualize the insertion tool as it is being positioned. Despite the slight difference, the clinician is in control throughout and manually inserts the insertion tool for both devices.
- **Adjustment of prostate model in the event of patient movement** - iSR'obot Mona Lisa 2.0 provides an adjustment panel for users to manually adjust the prostate model to align with the ultrasound live image of the shifted prostate. Artemis tracks the position and orientation of the ultrasound probe, and users mark landmark features on the ultrasound live image to enable its software to automatically adjust the prostate model to align with the ultrasound live image of the shifted prostate.
- **Information for active surveillance** - Artemis is intended to be used for patients in active surveillance to keep track of previous procedures information and outcomes. iSR'obot Mona Lisa 2.0 allows previous procedures information to be accessed for patients under active surveillance, but the histopathological outcome is not currently captured in the software.

The technological characteristic above are features that assists physicians to plan and insert an insertion tool. The physician has full control of the tasks to be performed. According to the risk analysis, non-clinical performance tests, device verification and validation tests, the above differences do not result in additional or increase to existing known risks for iSR'obot Mona Lisa 2.0.

Substantial Equivalence

The technological characteristics such as intended use, method of operation, general function and application of the iSR'obot Mona Lisa 2.0 are equivalent to the primary predicate iSR'obot Mona Lisa 1.0 (K203659),

iSR'obot Mona Lisa 1.0 (K203659), iSR'obot MRI-US Fusion (K161109) and iSR'obot Biopsy Kit (K163502) shall be collectively known as iSR'obot Mona Lisa 1.0 System.

Risk analysis was conducted to evaluate the modifications and features update in iSR'obot Mona Lisa 2.0. All verification and validation activities were performed and results demonstrated substantial equivalence. Table 1 indicates the comparison between the subject device and predicate devices.

Table 1: Comparison Between Predicate Devices and Subject Device iSR'obot Mona Lisa 2.0			
Technological Characteristic	**Reference Device:** **Eigen's Artemis (K162474)**	**Predicate Device:** **iSR'obot Mona Lisa 1.0 System (Primary - K203659, Reference - K161109, K163502)**	**Submitted Device:** **iSR'obot Mona Lisa 2.0**
Intended Use	Artemis along with the Needle Guide Attachment is used for image-guided interventional and diagnostic procedures of the prostate gland. It provides 2D and 3D visualization of Ultrasound (US) images and the ability to fuse and register these images with those from other imaging modalities such as Ultrasound, Magnetic Resonance, Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. The software also provides a virtual grid on the live ultrasound for	iSR'obot Mona Lisa 1.0 is intended for use by trained urologist or physician to perform the computer-assisted transperineal prostate biopsy under transrectal ultrasound guidance. The device serves as a biopsy needle guide only. It shall be used in conjunction with a third party ultrasound machine and endorectal probe that supports B-Mode, and a third party prostate biopsy gun and needle. The insertion of biopsy needle will be done by urologist. The patient is administered general anesthesia and placed in a lithotomy position.	iSR'obot Mona Lisa 2.0 is a user-controlled, stereotaxic accessory intended to guide physicians in the planning and positioning of insertion tools, such as a third-party needle or a probe, during image-guided diagnostic and interventional procedures in conjunction with the guidance of transrectal ultrasound involving the prostate gland in a clinical setting. Examples of such procedures include, but are not limited to, image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, and soft tissue ablations. The iSR'obot Mona Lisa 2.0 provides 2D and 3D visualization of Ultrasound images and the ability to fuse and register these images with those from other imaging modalities such as Magnetic

	performing systematic sampling of the target organ. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, reporting, and pathology management. Artemis is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers. Artemis is also intended to be used for patients in active surveillance to keep track of previous procedures information and outcomes.		Resonance, etc. It also provides the ability to display a simulated image of an insertion tool on a computer monitor screen, the target organ, and the current and projected future path of the insertion tool taking into account patient movement. Other software features include multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, and reporting.
Product Code	LLZ	IYO, ITX, LLZ, OIJ	IYO, ITX, LLZ, OIJ
Class	II	II	II
Target Anatomy	Prostate	Prostate	Prostate

Anatomy Access	Transperineal	Transperineal	Transperineal
	Transrectal	Not available	Not available
Patient population	Patients for a biopsy procedure Patients for an interventional procedure Patients in active surveillance	Patients for a biopsy procedure	Patients for a biopsy procedure Patients for an interventional procedure
Clinical Utility	Soft tissue biopsies, Soft tissue ablations Placement of fiducial markers Pathology management Patient data management	Soft tissue biopsies	Soft tissue biopsies Soft tissue ablations
Software			
Window OS	Yes	Yes	Yes
Medical Imaging Software	Yes	Yes	Yes
Compliance with FDA Cybersecurity	Yes	Yes	Yes (Updated)
Image Display			
Multi-Modality Support	Yes	Yes	Yes
General Image 2D/3D Review	Yes	Yes	Yes
3D Rendering View	Yes	Yes	Yes
Live 2D Ultrasound	Yes	Yes	Yes
Image Processing			

Gland Segmentation	Yes	Yes	Yes
Image Registration	Yes	Yes	Yes
Rigid Registration	Yes	Yes	Yes
Elastic Registration	Yes	Yes	Yes
Multi-Planar Reformatting	Yes	Yes	Yes
Connectivity			
DICOM Import/Export	Yes	Not available	Yes (updated)
Review Tools			
Standard Image Viewing Tools	Yes	Yes	Yes
Measurement Tools	Yes	Yes	Yes
Annotation Tools	Yes	Yes	Yes
Segmentation Tools	Yes	Yes	Yes
Reporting Tools	Yes	Yes	Yes
Image Overlays	Yes	Yes	Yes (updated)
Post Procedure Review	Yes	Not available	Yes
Planning & Navigation			
Import Prior Plans	Yes	Yes	Yes
Import/Add Targets	Yes	Yes	Yes
Plan / Mark Locations	Yes	Yes	Yes (updated)

Navigation Type	Mechanical	Electromechanical	Electromechanical
Third-Party Devices Compatibility			
Insertion Tools (e.g needles and probes)	Yes	Yes	Yes
Ultrasound Systems	Yes	Yes	Yes
Components			
Hardware	• Workstation • Mechanical Arm for positioning of insertion tool	• Workstation • Mechanical Arm for positioning of insertion tool • Stabilizer	• Workstation • Mechanical Arm for positioning of insertion tool • Stabilizer
Disposables	Not available	Proprietary Disposables	Proprietary Disposables

Safety and Effectiveness

The labelling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk management is ensured via Biobot Surgical's design control procedures and application of risk management procedure, which is used to identify and mitigate potential hazards. These potential hazards are controlled through the product development process, verification and validation testing, systematic clinical literature review and clinical effects analysis (CEA) to ensure safe profile of iSR'obot Mona Lisa 2.0.

Nonclinical Testing and Performance Information

Biobot performed the following testing to ensure safety and effectiveness of iSR'obot Mona Lisa 2.0:

- **Design and System Verification** - To ensure iSR'obot Mona Lisa 2.0 meets the specifications and its intended purpose
- **Software Verification and Validation** – To ensure the all software meets the specifications and the intended purpose. Software life cycle process is in accordance with IEC 62304:2006+A1:2015 Ed 1.1
- **Usability Testing** - Testing conducted in accordance with IEC 623661: 2015+AMD1: 2020 Ed 1.1 and FDA guidance Applying Human Factors and Usability Engineering to Medical Devices

- **Cybersecurity Testing** – Testing conducted in accordance with ANSI UL 2900-1 and ANSI UL 2900-2-1
- **Non-clinical System Performance Testing (system level testing using phantom)**
  - Testing conducted to demonstrate that after the system has been calibrated, the system is able to accurately position the needle.
  - Testing conducted to demonstrate the adjustment of the generated prostate models and planned needle position to compensate for the patient movement during the procedure.
  - Testing conducted to demonstrate multi-needle positioning
- **Biocompatibility testing –** Testing conducted to ensure biocompatibility of Needle Guide Holder.
  - ISO 10993-1:2018
  - ISO 10993-5: 2008
  - ISO 10993-10: 2010
  - ISO 10993-11: 2017
- **Reprocessing Validation –** to validate the cleaning and sterilization procedure for Needle Guide Holder. Testing is conducted in accordance with AAMI TIR12:2010 and AAMI TIR30:2011/ (R)2016.
- **Other Non-Clinical Tests**
  - IEC 60601-1:2005 Ed 3.1
  - IEC 60601-1-2:2014 Ed 4
  - IEC 60601-1-6:2013 Ed 3.1
  - ISO 14971:2019
  - ISTA 3A 2018
  - ISTA 3B 2017
  - AAMI TIR28

Clinical Information

There is no pre-market clinical investigation submitted for iSR'obot Mona Lisa 2.0.

Conclusion

Comparison of the intended use, indications for use, technological characteristics, and performance specifications demonstrate the functional equivalence of iSR'obot Mona Lisa 2.0 to the predicate device iSR'obot Mona Lisa 1.0.

Based on the conformance to standards, development under Biobot's quality system, and the successful verification and non-clinical testing, iSR'obot Mona Lisa 2.0 does not raise any new safety and/or effectiveness concerns. Biobot believes that the iSR'obot Mona

Lisa 2.0 is safe and effective, and performs in a substantially equivalent manner to the predicate device iSR'obot Mona Lisa 1.0.