Biobot Surgical Pte Ltd
℅ Lim Yan Shin
Regulatory Affairs
Woodlands Spectrum I
2 Woodlands Sector l #03-10
Singapore, Singapore 738068
SINGAPORE

July 8, 2021

Re: K203659
Trade/Device Name: iSR'obot Mona Lisa 1.0
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: March 28, 2021
Received: June 1, 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,

For

Thalia T. Mills, Ph.D.
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)*
K203659

Device Name
iSR'obot Mona Lisa 1.0

Indications for Use *(Describe)*
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.

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 - K203659

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


| | |
|---|---|
| Date: | May 27, 2021 |
| Submitter: | Biobot Surgical Pte Ltd<br>Woodlands Spectrum I,<br>2 Woodlands Sector 1 #03-10,<br>Singapore 738068 |
| Primary Contact: | Lim Yan Shin, Regulatory Affairs<br>Biobot Surgical Pte Ltd<br>Cell: +65 97263992<br>E-mail: yanshin.lim@ziggroup.com.sg |
| Secondary Contact: | Georgiann Keyport, Regulatory Consultant, U.S.<br>Email: gkeyport@canopyregulatory.com<br>Cell: 952-994-8267 |


**Product Identification**

| | |
|---|---|
| Device Trade Name: | iSR'obot Mona Lisa 1.0 |
| Common / Usual Name: | System, image processing, radiological |
| Classification Names: | 892.1560 Ultrasonic pulsed echo imaging system<br>892.1570 Diagnostic ultrasonic transducer |
| Product Code: | IYO, ITX |
| Manufacturer / Design Location: | Biobot Surgical Pte Ltd<br>Woodlands Spectrum I, 2 Woodlands Sector 1 #03-10, Singapore 738068 |

## Device Description

The iSR'obot Mona Lisa 1.0 is able to display the 2D live image feeds from commercially available ultrasound systems and also construct 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. The device is a user-controlled, stereotaxic accessory intended to guide the urologist or physician in the planning and

positioning of a needle during ultrasound-guided transperineal prostate procedures such as biopsies in the operating room.

The iSR'obot Mona Lisa 1.0 comprises a workstation, robotic navigation module (comprising of robotic arm and bed rail stabilizer), and disposables.

**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 1.0. Using the UroBiopsy 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 UroFusion 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.

**Robotic Navigation Module**

The robotic navigation module comprises 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 pivot 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 pivoting of the needle guidance mechanism are 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 biopsy procedure, the real-time 2D ultrasound image is visible on the iSR'obot Mona Lisa 1.0 display. After the robotic arm has pivoted based on 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 biopsy cores were taken. 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.

**Disposables**

The iSR'obot Biopsy Kit is intended to be used with the iSR'obot Mona Lisa 1.0 for performing a transperineal prostate biopsy. The kit consists of a plastic needle guide, probe sheath, and drape. The probe sheath provides a protective cover system for the ultrasound transducer usage in the rectum to prevent microbial and other contamination. The needle guide serves as guidance for a biopsy needle during the procedure.

The iSR'obot Mona Lisa 1.0 is used as a system with other currently cleared medical devices:

- iSR'obot MRI-US Fusion software (K161109)
- iSR'obot Biopsy Kit (K163502)

## Intended Use

iSR'obot Mona Lisa 1.0 serves as a biopsy needle guide to assist the urologist or physician in performing targeted transperineal prostate biopsy in adult males in conjunction with the guidance of transrectal ultrasound.

## Indications for Use

iSR'obot Mona Lisa 1.0 is intended for use by a 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.

## Predicate Device Information and Comparison

| Predicate Device Name | Predicate 510(k) Submission Reference |
|---|---|
| iSR'obot Mona Lisa | K130944 |

## Technology Characteristics Compared to Predicate Device

iSR'obot Mona Lisa 1.0 employs the same fundamental scientific technology (design, function and specifications) as that of its predicate device, iSR'obot Mona Lisa (K130944).

Similarities in technology characteristics include:

- Platform-hosted motorized devices and are able to provide a transverse view and a 3D view of the prostate gland;
- Use the same technology to acquire a transrectal ultrasound image to plan and guide a needle for a diagnostic procedure;
- Control the trajectory and depth for needle placement via needle guiding mechanism.

## Modification to iSR'obot Mona Lisa 1.0

iSR'obot Mona Lisa 1.0 has a workstation with a detachable control box and a projected capacitive touch screen monitor. One new component, Bed Rail Stabilizer, is included as a bed rail mounting structure for the Robotic Arm. The Robotic Arm has an improved needle guide holder.

iSR'obot Mona Lisa 1.0 is adding two new features in the UroBiopsy application software, which is a component of the cleared device. The new features are designed to 1) facilitate user management and 2) allow 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.

Other changes include minor user interface variations such as industrial design and 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.

## Substantial Equivalence

The technological characteristics such as intended use, indications for use, method of operation, general function and application of the iSR'obot Mona Lisa 1.0 are equivalent to the cleared predicated device iSR'obot Mona Lisa (K130944). Risk analysis was conducted to evaluate the modifications and features update in iSR'obot Mona Lisa 1.0. All verification and validation activities were performed and results demonstrated substantial equivalence. Table 1 indicates the comparison between the two devices.

**Table 1: Comparison Between Predicate Device iSR'obot Mona Lisa (K130944) and Subject Device iSR'obot Mona Lisa 1.0**

| Technical Characteristics | Predicate Device: iSR'obot Mona Lisa (K130944) | Subject Device: iSR'obot Mona Lisa 1.0 (Pending) |
|---|---|---|
| Intended Use | iSR'obot Mona Lisa serves as a biopsy needle guide to assist the surgeon in | iSR'obot Mona Lisa 1.0 serves as a biopsy needle guide to assist the urologist |

| Table 1: Comparison Between Predicate Device iSR'obot Mona Lisa (K130944) and Subject Device iSR'obot Mona Lisa 1.0 | | |
|---|---|---|
| **Technical Characteristics** | **Predicate Device: iSR'obot Mona Lisa (K130944)** | **Subject Device: iSR'obot Mona Lisa 1.0 (Pending)** |
| | performing a targeted transperineal prostate biopsy in adult males in conjunction with the guidance of transrectal ultrasound. | or physician in performing a targeted transperineal prostate biopsy in adult males in conjunction with the guidance of transrectal ultrasound. |
| Indication for Use | iSR'obot Mona Lisa is intended for use by a 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 the biopsy needle will be done by a urologist. | iSR'obot Mona Lisa 1.0 is intended for use by a 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 the biopsy needle will be done by a urologist. The patient is administered general anesthesia and placed in a lithotomy position. |
| Product Code | IYO, ITX | IYO, ITX |
| Class | II | II |
| Target Anatomy | Prostate | Prostate |
| Anatomy Access | Transperineal | Transperineal |
| **Software** | | |
| Operating System | Windows 7 Embedded | Windows 10 IoT Enterprise |
| Medical imaging software | Yes | Yes |

| Table 1: Comparison Between Predicate Device iSR'obot Mona Lisa (K130944) and Subject Device iSR'obot Mona Lisa 1.0 | | |
|---|---|---|
| **Technical Characteristics** | **Predicate Device: iSR'obot Mona Lisa (K130944)** | **Subject Device: iSR'obot Mona Lisa 1.0 (Pending)** |
| Compliance with FDA Cybersecurity | No | Yes |
| **Image Display** | | |
| Multi-Modality Support | Yes | Yes |
| General Image 2D/3D Review | Yes | Yes |
| 3D Rendering View | Yes | Yes |
| Live 2D Ultrasound | Yes | Yes |
| **Image Processing** | | |
| Gland Segmentation | Yes | Yes |
| Image Registration | Yes | Yes |
| Rigid Registration | Yes | Yes |
| Elastic Registration | Yes | Yes |
| Multi-Planar Reformatting | Yes | Yes |
| **Review Tools** | | |
| Standard Image Viewing Tools | Yes | Yes |
| Measurement Tools | Yes | Yes |
| Annotation Tools | Yes | Yes |
| Segmentation Tools | Yes | Yes |
| Reporting Tools | Yes | Yes |
| Image Overlay | Yes | Yes |
| **Planning & Navigation** | | |
| Import Prior Plans | Yes | Yes |
| Import/Add Targets | Yes | Yes |
| Plan/Mark Locations | Yes | Yes (with technological improvements) |
| Navigation Type | Electromechanical | Electromechanical |
| **Third-Party Devices Compatibility** | | |
| Needle e.g., biopsy | Yes | Yes |
| Ultrasound systems | Yes | Yes |
| **Components** | | |

| Table 1: Comparison Between Predicate Device iSR'obot Mona Lisa (K130944) and Subject Device iSR'obot Mona Lisa 1.0 | | |
|---|---|---|
| **Technical Characteristics** | **Predicate Device: iSR'obot Mona Lisa (K130944)** | **Subject Device: iSR'obot Mona Lisa 1.0 (Pending)** |
| Hardware | • Workstation<br>• Robotic Navigation Module | • Workstation<br>• Robotic Navigation Module |
| Disposable | iSR'obot Biopsy Kit (K163502) | iSR'obot Biopsy Kit (K163502) |

## Safety and Effectiveness

The labeling 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 Risk Management procedure, which is used to identify potential hazards because of the proposed changes. These potential hazards are controlled through the product development process, verification and validation testing, systematic clinical literature review, and clinical effects analysis (CEA) to establish a safe profile of iSR'obot Mona Lisa 1.0.

## Non-Clinical Testing

Biobot performed the following testing to ensure safety and effectiveness of iSR'obot Mona Lisa 1.0:

- **Design and System Verification** - To ensure the iSR'obot Mona Lisa 1.0 meets the specifications.
- **Software Verification and Validation** – To ensure the UroBiopsy application software meets the specifications and user needs. UroBiopsy is developed in accordance with IEC 62304:2006+A1:2015 Ed 1.1
- **Usability Testing** - To ensure no user error could impact the safety and performance of the device. 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 Simulation 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.
- **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
- IEC 62304:2006+A1:2015 Ed 1.1
- ISO 14971:2019
- ISTA 3A 2018
- ISTA 3B 2017

## Clinical Performance

There is no clinical investigation on iSR'obot Mona Lisa 1.0.

Systematic peer-review literature and clinical effect analysis were conducted to evaluate and demonstrate that the use of iSR'obot Mona Lisa 1.0 for Transperineal Prostate Biopsy (TPBx) is safe, without adding new risks or increasing risk levels for the users, including patients and clinical staffs.

iSR'obot Mona Lisa 1.0 has demonstrated substantial equivalence to the legally marketed predicate device iSR'obot Mona Lisa (K130944) with the following attributes:

- Design features;
- Intended Use;
- Indications for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

## Conclusion

Comparison of the intended use, indications for use, technological characteristics, and performance specifications demonstrate the functional equivalence of iSR'obot Mona Lisa 1.0 to the legally marketed predicate device, iSR'obot Mona Lisa (K130944).

Based on the conformance to standards, development under Biobot's quality system, and the successful verification and non-clinical testing, iSR'obot Mona Lisa 1.0 does not raise any new safety and/or effectiveness concerns. Biobot believes that the iSR'obot Mona Lisa 1.0 is safe and effective and performs in a substantially equivalent manner to the predicate device.