December 21, 2023

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

Re: K232320
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: December 7, 2023
Received: December 7, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232320

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.

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510(k) Summary

K232320

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 30, 2023
Submitter:	79 Ayer Rajah Crescent, #04-05, Singapore 139955
Primary Contact:	Lim Yan Shin Regulatory Manager Biobot Surgical Pte Ltd Cell: +65 97263992 E-mail: limyanshin@biobotsurgical.com
Secondary Contact:	Georgiann Keyport, Regulatory Consultant, U.S. Email: gkeyport@canopyregulatory.com Cell: 952-994-8267

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

System Overview

The iSR'obot Mona Lisa 2.0 system consists of a workstation, robotic navigation module (comprising of a motorized mechanical robotic arm, bed rail stabilizer or floor stand stabilizer) and disposables. The workstation is installed with application software that provides functions for image processing, image segmentation, 2D/3D visualization to support urologists or physicians in planning needle positions for procedures. The application software (UroBiopsy / UroTherapy) interfaces and controls the robotic arm to position its needle guidance mechanism at a trajectory to allow needle insertion by the physician. Another application software (UroFusion) provides an interface for users to perform contouring of the prostate gland and marking of suspected lesion regions, which can be imported into UroBiopsy or UroTherapy for image fusion during the procedure. The physician is able to review procedural data such as

prostate information and model, needle positioning plan and trajectories, number of needles executed, etc., using a utility software (UroReview). A utility software (UroConnect) provides the connectivity solution to a picture archiving and communication system (PACS) server for downloading/uploading DICOM-compatible data. The bed rail stabilizer and floor stand stabilizer provide support for the robotic arm. They are to be attached to the bed rail or mounted on the floor respectively. Sterile disposables are used with iSR'obot Mona Lisa 2.0 during prostate procedures.

The system is compatible with commercially available ultrasound systems, transrectal ultrasound bi-plane probes, and commercially available needle devices.

Predicate Device Information and Comparison

Predicate Device Name	Predicate 510(k) Submission Reference
iSR'obot Mona Lisa 2.0	K213411

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 Device

iSR'obot Mona Lisa 2.0 employs the same fundamental scientific technology (design, function, and specifications) as its original device, iSR'obot Mona Lisa 2.0 (K213411).

Similarities in technology characteristics include:

- Platform-hosted motorized devices 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 and interventional procedures;

- 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;
- Visualization of simulated images in an interventional procedure of 1) the lesions and their margins and 2) the treatment zone;
- 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

Modification to iSR'obot Mona Lisa 2.0

iSR'obot Mona Lisa 2.0 is modified:

- Material change to the needle guide holder accessory from stainless steel 316L (intended to be reusable) to polycarbonate and stainless steel 304 (intended to be disposable).
- Needle guide holder is included as new component in the disposable kit.
- A new list of ultrasound transducers tested as compatible to iSR'obot Mona Lisa 2.0:

Manufacturer	Compatible Transducer	510(k) Number
B-K MEDICAL APS	BK 8848	K132335
B-K MEDICAL APS	BK 0948	K173569, K180737, K223830
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	6L7Bs	K171579
Hitachi Healthcare Americas Corporation	CL4416R	K171708, K181376

- Other minor changes such as the software updates, the inclusion of a Floor Stand Stabilizer, and an iSR'obot Biopsy Kit (K163502) in the system. These changes do not significantly affect the 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

Comparison Between Subject Device and Predicate Device		
Technological Characteristic	**Predicate Device:** **iSR'obot Mona Lisa 2.0 (K213411)**	**Submitted Device:** **iSR'obot Mona Lisa 2.0 (K232320)**
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.	Same
Product Code	IYO, ITX, LLZ, OIJ	Same
Class	II	Same
Target Anatomy	Prostate	Same

Comparison Between Subject Device and Predicate Device		
Technological Characteristic	**Predicate Device:** **iSR'obot Mona Lisa 2.0 (K213411)**	**Submitted Device:** **iSR'obot Mona Lisa 2.0 (K232320)**
Anatomy Access	Transperineal	Same
Patient population	Patients for a biopsy procedure Patients for an interventional procedure	Same
Clinical Utility	Soft tissue biopsies Soft tissue ablations	Same
Software		
Window OS	Yes	Same
Medical Imaging Software	Yes	Same
Compliance with FDA Cybersecurity	Yes	Yes (Updated Non-significant Change)
Image Display		
Multi-Modality Support	Yes	Same
General Image 2D/3D Review	Yes	Same
3D Rendering View	Yes	Same
Live 2D Ultrasound	Yes	Same
Image Processing		
Gland Segmentation	Yes	Same
Image Registration	Yes	Same
Rigid Registration	Yes	Same
Elastic Registration	Yes	Same
Multi-Planar Reformatting	Yes	Same
Connectivity		
DICOM Import/Export	Yes	Same
Review Tools		

Comparison Between Subject Device and Predicate Device		
Technological Characteristic	**Predicate Device:** **iSR'obot Mona Lisa 2.0 (K213411)**	**Submitted Device:** **iSR'obot Mona Lisa 2.0 (K232320)**
Standard Image Viewing Tools	Yes	Same
Measurement Tools	Yes	Same
Annotation Tools	Yes	Same
Segmentation Tools	Yes	Same
Reporting Tools	Yes	Same
Image Overlays	Yes	Same
Post Procedure Review	Yes	Same
Planning & Navigation		
Import Prior Plans	Yes	Same
Import/Add Targets	Yes	Same
Plan / Mark Locations	Yes	Same
Navigation Type	Electromechanical	Same
Third-Party Devices Compatibility		
Insertion Tools (e.g needles and probes)	Yes	Same
Ultrasound Systems	Yes	Same
List of compatible ultrasound systems	B-K MEDICAL - BK 8848	Expanded list of compatible ultrasound: • B-K MEDICAL - BK 8848 • B-K MEDICAL - BK 0948 • Shenzhen Mindray - 6L7Bs • Hitachi - CL4416R
Hardware		
Workstation	Yes	Same
Mechanical Arm for Positioning of Insertion Tool	Yes. Robotic.	Same
Stabilizer	Bed Rail Stabilizer	• Bed Rail Stabilizer • Floor Stand Stabilizer (New)
Accessory & Disposable		
Needle Guide Holder	Yes	• No (removed and added in the disposables)

Comparison Between Subject Device and Predicate Device		
Technological Characteristic	**Predicate Device:** **iSR'obot Mona Lisa 2.0 (K213411)**	**Submitted Device:** **iSR'obot Mona Lisa 2.0 (K232320)**
Proprietary Disposables	iSR'obot Kit	• iSR'obot Kit (updated) • iSR'obot Biopsy Kit (K163502)
Needle Guide Holder Material	Stainless Steel 316 L	Polycarbonate and stainless steel 304

The technological characteristics such as intended use, indications for use, method of operation, general function, and application of the subject device iSR'obot Mona Lisa 2.0 are equivalent to the cleared predicated device iSR'obot Mona Lisa 2.0 (K213411). 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 the results demonstrated substantial equivalence.

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 as a result of the proposed changes. These potential hazards are controlled through the product development process, verification, and validation testing to ensure the safe profile of iSR'obot Mona Lisa 2.0.

Non-Clinical Testing

Biobot performed the following testing to ensure the safety and effectiveness of iSR'obot Mona Lisa 2.0 using well-established methods based on FDA recognized standards:

- **Design and System Verification** - To ensure new modification meets the specifications and its intended purpose
- **Software Verification and Validation** – To ensure all software updates meets the specifications and the intended purpose. Software life cycle process is in accordance with IEC 62304:2006+A1:2015 Ed 1.1
- **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 system is able to accurately position the needle with the new needle guide holder and iSR'obot Biopsy Kit.
- **Biological evaluation and biocompatibility testing –** Evaluation and testing conducted in accordance with ISO 10993-1:2018.
- **Sterilization validation –** Validation conducted in accordance with ISO 11135:2014

- **Compatible evaluation for the new ultrasound transducers –** compatibility evaluation conducted with the new ultrasound transducers (eg image quality, acoustic output, physical integrity with the holder)
- **Accelerated Aging –** accelerated aging, post-packaging and functional test conducted for the kit to demonstrate shelf life of 2 years
    - ASTM F1980-21
    - ASTM F1886/F1886M-16
    - ASTM F2906-11 (2019)
    - ASTM F1929-15
    - ASTM F88/F88M-21
- **Other Non-Clinical Tests**
    - ISO 14971:2019
    - ISTA 3A 2018

Clinical Performance

No clinical data is submitted in support of this submission.

The subject device iSR'obot Mona Lisa 2.0 did not require clinical study, since substantial equivalence to the legally marketed predicate device iSR'obot Mona Lisa 2.0 (K213411) was demonstrated 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 subject device iSR'obot Mona Lisa 2.0 to the legally marketed predicate device, iSR'obot Mona Lisa 2.0 (K213411).

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 different questions of safety and/or effectiveness. Biobot believes that the iSR'obot Mona Lisa 2.0 performs substantially equivalent to the predicate device.