Biobot Surgical Pte Ltd
% Ms. Lai Chee Liew
Head of Quality and Regulatory Affairs
79, Ayer Rajah Crescent
#04-06, Singapore 139955
SINGAPORE

Re: K163502
  Trade/Device Name: iSR’obot Biopsy Kit
  Regulation Number: 21 CFR 892.1570
  Regulation Name: Diagnostic Ultrasonic Transducer
  Regulatory Class: II
  Product Code: ITX, OIJ
  Dated: April 25, 2017
  Received: May 1, 2017

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.

May 16, 2017
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
510(k) Number (if known)
K163502

Device Name
iSR'obot Biopsy Kit

Indications for Use (Describe)

The iSR’obot Biopsy Kit (consisting of a needle guide, a probe sheath and a drape) is intended to be used with the iSR’obot Mona Lisa (K130944) for performing image guided transperineal biopsies of the prostate.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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 807.92.

Date: May 16, 2017

Submitter: Biobot Surgical Pte Ltd
79, Ayer Rajah Crescent,
#04-06, Singapore 139955

Primary Contact: Lai Chee Liew
Head of Quality and Regulatory Affairs
Biobot Surgical Pte Ltd
Telephone: +65 63511868
E-mail: laichee@zicomgroup.com

Product Identification

Device Trade Name: iSR’obot Biopsy Kit
Common / Usual Name: Biopsy Kit
Classification Names/: 21 CFR 892.1570, Diagnostic Ultrasound Transducer / ITX
Product Code: 21 CFR 892.1560, Ultrasonic pulsed echo imaging system / OIJ (Biopsy Needle Guide Kit)

Predicate Device(s):
K970515 CIVCO Latex Ultrasound Transducer Cover (Primary Predicate)
K971115 Transrectal Needle/Biopsy Guide (Reference Device)
K844472 Civco Scan Drape (Reference Device)

Manufacturer/Design Location: Biobot Surgical Pte Ltd
79 Ayer Rajah Crescent, #04-06
Singapore 139955
Device Description

The iSR'obot Biopsy Kit is a consumables pack consisting of three (3) separate single-use items designed to be used with the iSR'obot Mona Lisa (K130944).

Contents of the Biopsy Kit

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probe Sheath</td>
<td>Non-active invasive device made of medical grade TPX (polymethylpentene). The open end of the sheath is intended to be connected to the end of the probe platform of Mona Lisa and its closed end is to be inserted into the patient’s rectum for transient use (&lt; 1 hour) during the prostate biopsy process. The device functions as a sheath to an ultrasound probe providing a stabilized channel for ultrasound scanning of the prostate organ.</td>
</tr>
<tr>
<td>Needle Guide (for 18G needle)</td>
<td>Non-active non-invasive device medical grade PP (Polypropylene). It is to be mounted on the Mona Lisa, functioning as a channel for a biopsy needle. The head of the needle guide will touch the pivot point (puncture hole) on the patient’s perineal skin during the biopsy process.</td>
</tr>
<tr>
<td>Drape</td>
<td>An accessory made of plastic (Low Density Polyethylene - Titanlene) with silicone rings. It is intended to be used as a cover for the iSR’obot Mona Lisa during the biopsy process for the purpose of prevention of contamination.</td>
</tr>
</tbody>
</table>

The components are assembled into a Tyvek Film Pouch which is made up of Tyvek 1059B and a PET/PE laminated 52µm transparent film. The Tyvek 1059B is highly resistant to penetration by bacterial spores and other contaminating microorganisms. Microbial barrier test conducted on the Tyvek film pouch showed that the pouch can maintain sterility for the 3 years shelf-life of the Biopsy kit if packaging integrity is not compromised.

The final kit assembled in a cleanroom is sterilized using ethylene oxide.

Biopsy Papers (not considered a medical device) are included with the kit as a convenience to the user. The hospital has the option of using biopsy specimen collection products generally supplied in the hospital.

Hardware Description

There is no hardware component in the Biopsy Kit

Intended Use

The iSR’obot Biopsy Kit is intended to be used with the iSR’obot Mona Lisa (K130944). The probe sheath provide a protective cover system for the ultrasound transducer usage in the rectum to prevent microbial and other contamination. The needle guide serves as a guidance for a biopsy needle during the procedure.
### Indications for Use

The iSR’obot Biopsy Kit (consisting of a needle guide, probe sheath and drape) is intended to be used with the iSR’obot Mona Lisa (K130944) for performing image guided transperineal biopsies of the prostate.

### Technology

The subject and predicate devices are designed for secure and aligned fit to the transducer and biopsy needle while not altering transducer nor biopsy needle design integrity nor function.

The table below outlines the major subsystem differences and similarities.

1. **Probe Sheath**

<table>
<thead>
<tr>
<th></th>
<th>Predicate Device: CIVCO Latex Ultrasound Transducer Cover</th>
<th>Proposed Device: iSR’obot Biopsy Kit</th>
<th>Discussion of Similarities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Civco</td>
<td>Biobot</td>
<td></td>
</tr>
<tr>
<td>510(k) number</td>
<td>K970515</td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Where Used</td>
<td>Hospital</td>
<td>Hospital</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Protective cover or sheath placed over diagnostic transducer/probe instruments</td>
<td>The probe sheath provide a protective cover system for the ultrasound transducer.</td>
<td>Same</td>
</tr>
<tr>
<td>Material</td>
<td>Natural rubber latex</td>
<td>Medical grade TPX (polymethylpentene)</td>
<td></td>
</tr>
<tr>
<td>Manufacturing</td>
<td>Dip-molding</td>
<td>Injection molding</td>
<td></td>
</tr>
<tr>
<td>Sterility</td>
<td>ETO</td>
<td>ETO</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>ISO10993</td>
<td>ISO10993.</td>
<td>Same</td>
</tr>
<tr>
<td>Disposition</td>
<td>Disposable</td>
<td>Disposable</td>
<td>Same</td>
</tr>
<tr>
<td>Human Factor</td>
<td>No Known Adverse Effects</td>
<td>No Known Adverse Effects</td>
<td>Same</td>
</tr>
<tr>
<td>Chemical Safety</td>
<td>Latex material formulations conform to US FDA CFR, Title 21, Section 177.2600</td>
<td>No Hazardous Components 29CFR1910, 1200</td>
<td></td>
</tr>
<tr>
<td>Mechanical Safety</td>
<td>Material strength and elasticity is adequate to allow use without tearing or pinholing the cover</td>
<td>Material strength and elasticity is adequate to allow use without breaking or cracking the sheath</td>
<td>Same</td>
</tr>
<tr>
<td>Anatomical site</td>
<td>Body surface, endocavity where ultrasound is used</td>
<td>Rectum where ultrasound probe goes in to scan the prostate</td>
<td>Similar</td>
</tr>
</tbody>
</table>
### 2. Needle Guide

<table>
<thead>
<tr>
<th></th>
<th>Predicate Device: Transrectal Needle/Biopsy Guide</th>
<th>Proposed Device: iSR’obot Biopsy Kit</th>
<th>Discussion of Similarities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Protek Medical Products Inc.</td>
<td>Biobot</td>
<td></td>
</tr>
<tr>
<td>510(k) number</td>
<td>K041637</td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Where Used</td>
<td>Hospital</td>
<td>Hospital</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Ultrasound transducer needle guide</td>
<td>Biopsy needle guide</td>
<td>Similar</td>
</tr>
<tr>
<td>Materials</td>
<td>Stainless Steel; Medical Grade Plastic</td>
<td>Medical Grade PP (Polypropylene)</td>
<td>-</td>
</tr>
<tr>
<td>Sterility</td>
<td>ETO</td>
<td>ETO</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>ISO10993</td>
<td>ISO10993</td>
<td>Same</td>
</tr>
<tr>
<td>Chemical Safety</td>
<td>No Hazardous Components 29CFR1910,1200</td>
<td>No Hazardous Components 29CFR1910,1200</td>
<td>Same</td>
</tr>
<tr>
<td>Anatomical Sites</td>
<td>Where Ultrasound is Used</td>
<td>Perineal Area (Skin)</td>
<td>-</td>
</tr>
<tr>
<td>Manufacturing Method</td>
<td>Injection molded clips</td>
<td>Injection molded</td>
<td>Same</td>
</tr>
<tr>
<td>Human Factor</td>
<td>No Known Adverse Effects</td>
<td>No Known Adverse Effects</td>
<td>Same</td>
</tr>
</tbody>
</table>

### 3. Drape

<table>
<thead>
<tr>
<th></th>
<th>Predicate Device: Civco Scan Drape</th>
<th>Proposed Device: iSR’obot Biopsy Kit</th>
<th>Discussion of Similarities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Civco</td>
<td>Biobot</td>
<td></td>
</tr>
<tr>
<td>510(k) number</td>
<td>K844472</td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Where Used</td>
<td>Hospital</td>
<td>Hospital</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Protective Cover or sheath placed over equipment to help prevent transfer of microorganisms, body fluids, etc</td>
<td>Cover for the iSR’obot Mona Lisa for the purpose of prevention of contamination</td>
<td>Same</td>
</tr>
<tr>
<td>Materials</td>
<td>Polyethylene</td>
<td>Low Density Polyethylene</td>
<td>Same</td>
</tr>
<tr>
<td>Sterility</td>
<td>ETO</td>
<td>ETO</td>
<td>Same</td>
</tr>
<tr>
<td>Human Factor</td>
<td>No Known Adverse Effects</td>
<td>No Known Adverse Effects</td>
<td>Same</td>
</tr>
</tbody>
</table>
Determination of Substantial Equivalence

Summary of Non-Clinical Tests

Testing on the probe sheath in the iSR’obot Biopsy Kit involved laboratory stress test to demonstrate mechanical safety. Performance testing to demonstrate effective ultrasound imaging of the prostate gland through the probe sheath was done using a phantom (comparison of ultrasound images with and without the probe sheath); as well as a review of images obtained during the clinical trial conducted for the main device - iSR’obot Mona Lisa (K130944).

The needle guide only serves as a channel for an 18 gauge biopsy needle. The physical dimensions were verified to ensure that an 18 gauge needle can pass through and any deflection of the needle is within the specified tolerance. Additionally both the probe sheath and needle guide met biocompatibility requirements specified by ISO 10993-01. Environmental, packaging, shipping, shelf-life and sterilization requirements were met through validations performed by a certified laboratory.

The iSR’obot Biopsy Kit consists of accessories which are the same as devices being marketed legally by several companies. The Biopsy Kit 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
- Performance testing (Verification)

Biobot believes that the Biopsy Kit is of comparable type and substantially equivalent to the predicate devices identified.
**Predicate Devices:**
1. CIVCO Latex Ultrasound Transducer Cover
2. Transrectal Needle/ Biopsy Guide
3. Civco Scan Drape

**Proposed Device:**
iSR’obot Biopsy Kit

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>1. Protective cover or sheath placed over diagnostic transducer/ probe instruments</th>
<th>1. The probe sheath provide a protective cover system for the ultrasound transducer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Ultrasound transducer needle guide</td>
<td>2. The needle guide serves as a guidance for a biopsy needle during the procedure</td>
</tr>
<tr>
<td></td>
<td>3. Protective Cover or sheath placed over equipment to help prevent transfer of microorganisms, body fluids, etc</td>
<td>3. The drape is a cover for the iSR’obot Mona Lisa during the biopsy process for the purpose of prevention of contamination</td>
</tr>
</tbody>
</table>

**Discussion**

The intended use of the iSR’obot Biopsy Kit is substantially equivalent to the predicate devices.

**Conclusion**

Biobot Surgical Pte Ltd believes that the iSR’obot Biopsy Kit is substantially equivalent with regard to Intended use and other key features including safety and effectiveness to the predicate devices.