Section 5: 510(k) Summary

AUG 12 2011

The following information is provided as required by 21 CFR § 807.87 for the iSR'obot Mona Lisa 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: BioBot Surgical Pte Ltd.
Blk 55, Ayer Rajah Crescent #06-09
Singapore 139949
Establishment Registration: not yet assigned

Contact: M Squared Associates, Inc.
Cherita James
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Date of Submission: May 11, 2011

Proprietary Name: iSR'obot Mona Lisa

Common Name: system, image processing, radiological

Regulatory Class: II

Regulation(s): 892.1560 Ultrasonic pulsed echo imaging system
892.1570 Diagnostic ultrasonic transducer

Product Codes: IYO, ITX

Predicate Device(s): Envisioneering, LLC TargetScan Transrectal Ultrasound System K041639 and TargetScan Biopsy needle guide K041637

Device Description: iSR'obot Mona Lisa is a platform-hosted motorized device integrating a probe-driving system for 3-D image collection and a precise biopsy guidance mechanism (biopsy needle platform) to control the orientation of needle insertion and depth of puncture to assist the surgeon perform targeted transperineal prostate biopsy in conjunction with the guidance of transrectal ultrasound. The device serves as a needle guide only.
The device has a graphics user interface (GUI) that can provide a complete view of the 3D prostate to the physicians by hands-free image acquisition. The prostate segmentation tool

allows a manual or automatic surface detection from the 3D image, based on which the prostate volume is calculated and the systematic biopsy plan is generated. This plan can be customized and the approved plan will be used to control the biopsy needle platform to guide the needle positioning for the manual puncture.

Indications 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 biopsy needle will be done by urologist.

Intended Use: iSR'obot Mona Lisa serves as a biopsy needle guide to assist the surgeon in performing targeted transperineal prostate biopsy in adult males in conjunction with the guidance of transrectal ultrasound.

Technological Characteristics: Like TargetScan Transrectal Ultrasound System (K041639), the iSR'obot Mona Lisa utilizes similar technology to acquire transrectal ultrasound image to plan and guide a prostate biopsy procedure. Both devices provide transverse view, sagittal view and 3D view of prostate gland.

Regarding to the needle guiding mechanism, both iSR'obot Mona Lisa and TargetScan Biopsy needle guide (K041637) can identify the direction and depth for biopsy needle. Unlike TargetScan Biopsy needle guide (K041637) to adjust the direction and depth manually, iSR'obot Mona Lisa employs a 4-degree-of-freedom robotic guiding mechanism to identify the direction and depth of the biopsy needle.

Non-clinical Testing: Bench and simulated use testing, including phantom testing, confirm that the subject device performs as intended and is substantially equivalent to the predicate devices.

Clinical Performance: No clinical data is submitted in support of this submission.

Substantial Equivalence/Conclusions:

The claim of substantial equivalence of iSR'obot Mona Lisa to the products identified above is based on the comparison of the regulatory characteristics, product technical characteristics, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

BioBot Surgical PTE Ltd.
% Ms. Cherita James
Regulatory Consultant
M Squared Associates, Inc.
901 King St., Suite 200
ALEXANDRIA VA 22314

AUG 12 2011

Re: K111347
Trade/Device Name: iSR'obot Mona Lisa
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: May 11, 2011
Received: May 16, 2011

Dear Ms. James:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111347

Device Name: iSR'obot Mona Lisa

Indications 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 biopsy needle will be done by urologist.

Prescription Use ___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111347