DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 7, 2017

SmartTarget, Ltd.
℅ Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K170250
Trade/Device Name: SmartTarget
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 18, 2017
Received: May 19, 2017

Dear Mr. Job:

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.

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170250

Device Name

SmartTarget

Indications for Use *(Describe)*

The SmartTarget device is intended as an accessory for image-guided interventional and diagnostic procedures involving the prostate gland, and to be used by physicians for enhanced visualization of two-dimensional (2D) transrectal ultrasound TRUS images of the prostate in clinic and hospital settings. It allows the user to segment medical images and it performs three-dimensional (3D) reconstruction of digitized TRUS video images to form a 3D TRUS volume. The SmartTarget software provides 2D and 3D image visualization features, including the ability to review images, generate multi-planar views, annotate images, and identify and record the locations of instruments inserted during the procedure.

The device is intended to be used in diagnostic and treatment procedures in a clinical setting in which a needle or other instrument is inserted into the prostate through the perineum or urethra, or instruments that are positioned externally to the prostate so that treatment can be delivered to prostate tissue, or diagnostic information obtained from prostate tissue.

Example procedures include, but are not limited to: needle biopsy in which tissue samples are removed from the prostate; in situ diagnostic techniques, such as those based on optical sensing; thermal tissue ablation using radiofrequency, microwave, laser, cryotherapy, or high-intensity focused ultrasound; photodynamic therapy; irreversible electroporation; radioactive source implantation (brachytherapy); and locally-injected drug therapies

Type of Use *(Select one or both, as applicable)*

XX 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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Proprietary or Trade Name: SmartTarget

Common/Usual Name: Picture archiving and communications system

Classification Name: Picture archiving and communications system
LLZ, Class II, 21 CFR 892.2050

Predicate Device: Invivo Corporation UroNav K153073
Reference Devices: Focal Heathcare Inc. Fusion Bx K153166
Jet Soft SRL BioJet K122329

Device Description:
The SmartTarget software is designed for the fusion/registration of transrectal ultrasound (TRUS) images of the prostate with three-dimensional (3D) images, such as a magnetic resonance image (MRI) or x-ray computed tomography (CT) image etcetera, during procedures for which TRUS is used to provide real-time imaging of the prostate, nearby anatomical structures, and instruments inserted into the prostate to guide instrument placement. The software supports the following tasks: computer-assisted surgical planning, allowing target regions to be defined within the prostate in a diagnostic/planning image and TRUS images; reconstruction of 3D TRUS images from multiple US video frames, captured at pre-set intervals as the TRUS probe is translated or rotated; and image fusion/registration wherein the spatial relationship between prostate in the diagnostic/planning image and TRUS images is calculated. The system software reproduces and supplements the visual information provided by real-time TRUS images, and superimposes a graphical representation of one or more target regions on to the reproduced TRUS images. The target region(s) may represent a tumor, another tissue structure visible in the diagnostic/planning image, or a location of clinical relevance (such as a region from which tissue samples are to be removed).Displayed target regions provide additional information to the TRUS image, enabling the operating clinician to direct instruments to these regions.

Indications for Use:
The SmartTarget device is intended as an accessory for image-guided interventional and diagnostic procedures involving the prostate gland, and to be used by physicians for enhanced visualization of two-dimensional (2D) transrectal ultrasound TRUS images of the prostate in clinic and hospital settings. It allows the user to segment medical images and it performs three-dimensional (3D) reconstruction of digitized TRUS video images to form a 3D TRUS volume. The SmartTarget software provides 2D and 3D image visualization features, including the ability to review images, generate multi-planar views, annotate images, and identify and record the locations of instruments inserted during the procedure.

The device is intended to be used in diagnostic and treatment procedures in a clinical setting in which a needle or other instrument is inserted into the prostate through the perineum or urethra, or instruments that are positioned externally to the prostate so that treatment can be delivered to prostate tissue, or diagnostic information obtained from prostate tissue.

Example procedures include, but are not limited to: needle biopsy in which tissue samples are removed from the prostate; in situ diagnostic techniques, such as those based on optical sensing; thermal tissue ablation using radiofrequency, microwave, laser, cryotherapy, or high-intensity focused ultrasound; photodynamic therapy; irreversible electroporation; radioactive source implantation (brachytherapy); and locally-injected drug therapies.

Contraindications:
None

Device Comparison

Table 1 compares the subject device to the predicate UroNav (K153073) and the reference devices Fusion Bx (K153166) and BioJet (K122329). The reference devices have been included to support use of mechanical encoder technology whereas the predicate had used electromagnetic tracking.

Table 1 Comparison of Predicate and Reference Devices to Subject Device

Feature	Predicate Uronav K153073	Reference Device 1 Fusion Bx K153166	Reference Device 2 BioJet K122329	SmartTarget Proposed Device
Indications for Use	UroNav is a stereotaxic accessory 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 Magnetic Resonance (MR), Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire, grid plate 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. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements and 2D/3D image registration.	Fusion Bx is intended for use by physicians for enhanced visualization of ultrasound imaging of the prostate in clinic and hospital settings. It provides 2D and 3D image visualization including review, manipulation, and analysis tools. Additional features include patient data management, image measurement, multiplanar reconstruction, 3D image registration, segmentation, image annotation, and recording of the locations where the biopsies were acquired during the procedure.	The BioJet software is intended to be used by physicians in the clinic or hospital for 20 and 3D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multiplanar reconstruction, segmentation, image measurements, and 3-D registration.	The SmartTarget device is intended as an accessory for image-guided interventional and diagnostic procedures involving the prostate gland, and to be used by physicians for enhanced visualization of two-dimensional (2D) transrectal ultrasound TRUS images of the prostate in clinic and hospital settings. It allows the user to segment medical images and it performs three-dimensional (3D) reconstruction of digitized TRUS video images to form a 3D TRUS volume. The SmartTarget software provides 2D and 3D image visualization features, including the ability to review images, generate multi-planar views, annotate images, and identify and record the locations of instruments inserted during the procedure. The device is intended to be used in diagnostic and treatment procedures in a

	UroNav 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.			clinical setting in which a needle or other instrument is inserted into the prostate through the perineum or urethra, or instruments that are positioned externally to the prostate so that treatment can be delivered to prostate tissue, or diagnostic information obtained from prostate tissue. Example procedures include, but are not limited to: needle biopsy in which tissue samples are removed from the prostate; in situ diagnostic techniques, such as those based on optical sensing; thermal tissue ablation using radiofrequency, microwave, laser, cryotherapy, or high-intensity focused ultrasound; photodynamic therapy; irreversible electroporation; radioactive source implantation (brachytherapy); and locally-injected drug therapies.
Target anatomy	Prostate	Prostate	Prostate	Prostate
Anatomy access	Transperineal Transrectal	Transrectal	Transperineal Transrectal	Transperineal
Windows OS	Yes	Yes	Yes	Yes
Medical imaging software	Yes	Yes	Yes	Yes

Feature	Predicate Uronav K153073	Reference Device 1 Fusion Bx K153166	Reference Device 2 BioJet K122329	SmartTarget Proposed Device
3D rendering view	Yes	Yes	Yes	Yes
Multi-modality Support	Yes	Yes	Yes	Yes
Live 2D ultrasound	Yes	Yes	Yes	Yes
Gland segmentation	Yes	Yes	Yes	Yes
Image registration	Yes	Yes	Yes	Yes
Rigid registration	Yes	Yes	Yes	Yes
Elastic registration	Yes	Yes	No	Yes
Multi-planar reformatting (MPR)	Yes	Yes	Yes	Yes
DICOM import/export	Yes	Yes	Yes	Import but no export
Ultrasound video	Yes	Yes	Yes	Yes
Standard Image viewing tools	Yes	Yes	Yes	Yes
Measurement tool	Yes	Yes	Yes	No
Annotation tool	Yes	Yes	Yes	Yes
Segmentation tool	Yes	Yes	Yes	Yes

Feature	Predicate Uronav K153073	Reference Device 1 Fusion Bx K153166	Reference Device 2 BioJet K122329	SmartTarget Proposed Device
Video capture	Yes	Yes	Yes	Yes
Image overlays	Yes	Yes	Yes	Yes
Import prior plans	Yes	Yes	Yes	Yes
Import/Add targets	Yes	Yes	Yes	Yes
Plan/Mark locations	Yes	Yes	Yes	Yes
Navigation type	3D electromagnetic sensors attached to US probe	Position encoders attached to an articulated arm that holds a TRUS probe (part of device)	BioJet works with commercially available mechanical stepper and stabilizer assemblies that holds the ultrasound probe and tracks the probe position while the physician performs a normal ultrasound imaging procedure of the subject prostate. [This is an off-the-shelf device]	Position encoders attached to a mechanical US probe stepper device, which holds and secures the US probe by means of a cradle and clamping mechanism (third-party device)

Substantial Equivalence Discussion
We discuss the table above.

Indications for Use / Patient Population / Environment of Use:
As in comparison of Indications for Use above, we can conclude that the indications for use for the SmartTarget and the predicate are substantially equivalent. When compared to the reference device taking into consideration the device description, the SmartTarget and Fusion Bx are substantially equivalent.
Discussion:
The differences in proposed indications for use are minor: The UroNav device supports TRUS-guided procedures wherein instruments are inserted via either the transperineal or transrectal route, whereas SmartTarget does not support transrectal instrument insertion. These minor differences do not raise new risk or safety concerns, and the subject device can be found substantially equivalent.

Prescriptive:
The Smart Target, reference and predicate are prescription devices.
Discussion:
There are no differences, thus the subject device can be found substantially equivalent.

Design and Technology:
The SmartTarget utilizes the same technological characteristics as the predicate device.
Both:

- are PC based software applications that provide 2D and 3D medical image acquisition including ultrasound video image acquisition arid visualization of the prostate
- use the Windows operating systems
- allow co-registration of digitized live US images, which are reconstructed to form a 3D US image, to previously a created 3D image, transferred and stored as a set of DICOM image slices
- include image enhancements, such as contrast and brightness control
- provide patient and clinical data management features
- permit the digitization of live US video images received from commercially available imaging devices
- use graphical overlays to represent target regions of interest (such as tumors)
- calibrate US video images
- create a report
- allow multi-planar reformatting
- allow manual planning of instrument positioning including biopsy needle placement and planning
- allow the user to plan and mark the reached positions of the biopsies and instruments
- do not steer or in any way control the positioning of the instruments used
- do not control or influence in any way devices or processes used to treat tissue
- are only intended for use in TRUS-guided procedures involving the prostate.

The UroNav includes an Electromagnetic Measurement System (EMMS) for procedure navigation and instrument tracking. In this system, small EM sensors, attached to the TRUS probe, measure the 3D physical position and orientation of the probe. The SmartTarget interfaces with a third-party mechanical stepper device (such as CIVCO EX3 Stepper 510(k) K 131161) fitted with digital position encoders to determine the 3D position and orientation of the probe. This technology is similar to the reference devices which use position encoders.

Discussion:
The highlighted difference in navigation and tracking technique employed in the UroNav and SmartTarget devices does not significantly affect the use of the device and does not raise new or additional safety risks since these techniques may be considered alternative yet equivalent means of determining the location of the TRUS probe. The tracking technique is similar to the reference device (Fusion Bx) which uses position encoders attached to an articulated arm that holds a TRUS probe. In all other respects, the design and technology of the two devices are substantially equivalent.

Performance and Specifications:
Both the UroNav and SmartTarget have been subjected to non-clinical and performance testing procedures by designated individuals as required by the quality procedures of the respective manufacturers. Both devices, verification and validation test plans were designed to evaluate all input functions, output functions, and actions performed by each device in each operational mode.
Discussion:
There are no differences, thus the subject device can be found substantially equivalent.

Compliance with Standards:
SmartTarget uses commercial off-the-shelf hardware that is separately approved and that comply with AAMI/ANSI/ES 60601-1 and IEC 60601-1-2. The Uronav includes hardware and complies with IEC 60601-1 and IEC 60601-1-2.
Discussion:
Both the SmartTarget and the predicate device comply with the relevant standards and thus can be found substantially equivalent.

Nonclinical / Bench:
The SmartTarget was tested against its design specifications and all were met. Test phantoms incorporating synthetic prostates were used to verify the accuracy of both the image registration/fusion functionality and physical instrument placement error during guided needle insertion. From careful laboratory experiments, the measured image alignment error, determined as the linear distance between the locations of an image-visible target after registering ultrasound and MRI volumes was 2.0mm. The overall needle-tip placement error was 2.9mm. These errors are considered to be acceptable for the clinical applications for which the SmartTarget system is to be used.

Biocompatibility:
There are no patient contact parts of the SmartTarget device.

Substantial Equivalence Conclusion

Based upon the foregoing performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance we believe we have demonstrated that the SmartTarget is substantially equivalent to the predicate device.