DE NOVO CLASSIFICATION REQUEST FOR
PROSTATE MECHANICAL IMAGER

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Prostate lesion documentation system.** A prostate lesion documentation system is a prescription device intended for use in producing an image of the prostate as an aid in documenting prostate abnormalities previously identified during a digital rectal examination. The device uses pressure sensors and image reconstruction software to produce a prostate image that highlights regional differences in intraprostatic tissue elasticity or stiffness. The device is limited to use as a documentation tool and is not intended for diagnostic purposes or for influencing any clinical decisions.

NEW REGULATION NUMBER: 21 CFR 876.2050

CLASSIFICATION: CLASS II

PRODUCT CODE: OQT

BACKGROUND

DEVICE NAME: PROSTATE MECHANICAL IMAGER (PMI)

SUBMISSION NUMBER: DEN100016

DATE OF DE NOVO: MAY 21, 2010

CONTACT: NOUNE SARVAZYAN, PH.D.
CHIEF EXECUTIVE OFFICER
ARTANN LABORATORIES, INC.
1459 LOWER FERRY ROAD
TRENTON, NJ 08618

REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS II

INDICATIONS FOR USE

The Prostate Mechanical Imager (PMI) is indicated for the production of an elasticity image of the prostate as an aid in documenting prostate abnormalities that were previously identified by digital rectal examination (DRE). The device utilizes a transrectal probe with pressure sensor arrays and a motion tracking system and provides real-time elasticity images of the prostate. This device is limited to use as a documentation tool and therefore is not to be used for cancer diagnosis or for any other diagnostic purpose. This device is only to be used to image and document an abnormality that was already identified by DRE. Clinical

management decisions are not to be made on the basis of information from the PMI device, but rather on the basis of the DRE. If there is disagreement between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., prostate-specific antigen (PSA) levels) in accordance with standard medical practice.

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109.

Limitations on device use are also achieved through the following statements included in the user manual:

This device is limited to use as a documentation tool and therefore is not to be used for cancer diagnosis or for any other diagnostic purpose.

This device is only to be used to image and document an abnormality that was already identified by DRE.

Clinical management decisions are not to be made on the basis of information from the PMI device, but rather on the basis of the DRE. If there is disagreement between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., PSA levels) in accordance with standard medical practice.

This device has not been shown to be useful as a diagnostic or management tool; therefore, the device is not to be used for such purposes, e.g., to track changes in the size of a lesion, to guide biopsy needle placement, or as a replacement for digital rectal examination.

The system automatically includes the following statements (prominently displayed with all screen images, electronically saved reports, and printed reports containing images):

Not to be used for diagnostic purposes.

Not to be used for making clinical management decisions.

The labeling includes the following instructions to not save or print a report if the images do not agree with the prior digital rectal examination findings:

CAUTION: Examination data should not be saved if the recorded prostate images do not agree with the DRE findings.

Do not save the exam or print an examination report if the recorded prostate images do not agree with the DRE findings.

The labeling includes the following additional precautions addressing limitations applicable to specific patient populations:

This device has not been shown to be effective in patients who have undergone prostate surgery, radiation therapy, cryotherapy, or chemotherapy for prior prostate cancer.

This device should not be used on patients with open wounds of the rectum or areas around the prostate, as this may increase the risk of tissue trauma, bleeding, and infection.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Prostate Mechanical Imager (PMI) is an electronic palpation device that is meant to mimic the digital rectal examination (DRE) by generating images of pressure patterns of the palpated prostate. The information provided by the device is characterized as being similar in nature to the information obtained from a standard DRE (i.e., determination of regions of relative tissue hardness within the prostate) with the utility being that the results are visually displayed and can be electronically saved, transmitted, and/or printed out for documenting in patient's medical records.

Principle of Operation:

- An image of the prostate is generated by the device based on the measurement of the mechanical stress (pressure) patterns on the rectal wall over the prostate compressed by the transrectal probe.

- The device's ability to produce a color image of tissue abnormalities that were already detected by DRE is accomplished by sensing differences in elasticity/hardness between normal and abnormal tissues. The pressure patterns obtained through the rectal probe's array of 128 pressure sensors are recorded and used to generate 2-D and 3-D elasticity images of the prostate.

- The pressure sensor array, in response to the applied pressure, produces a pressure response pattern on a rectal wall covering the prostate, analogous to that sensed by the physician's finger palpating the prostate during a DRE. In general, normal tissue is less dense and more elastic, whereas cancerous tissue is firmer and less elastic. Elasticity in normal prostate tissue ranges between 15 and 30 kPa, whereas, the elasticity of most of prostate cancers ranges between 40 kPa and 300 kPa, which is an order of magnitude in hardness greater than normal tissue. With the PMI device, a series of cross-sectional images are obtained to

reconstruct the prostate and visualize the regions of varying tissue hardness within the prostate.

The PMI is a PC-based system consisting of the following components, which are pictured and described in more detail below:

(1) a hand-held transrectal probe with two pressure sensor arrays and a motion tracking system;

(2) a probe calibration chamber;

(3) a data acquisition unit;

(4) a central processing unit consisting of an off-the-shelf computer with proprietary software;

(5) an off-the-shelf touch screen monitor;

(6) an off-the-shelf color printer (optional);

(7) an off-the-shelf medical grade keyboard;

(8) a disposable probe sheath;

(9) a disposable system cover;

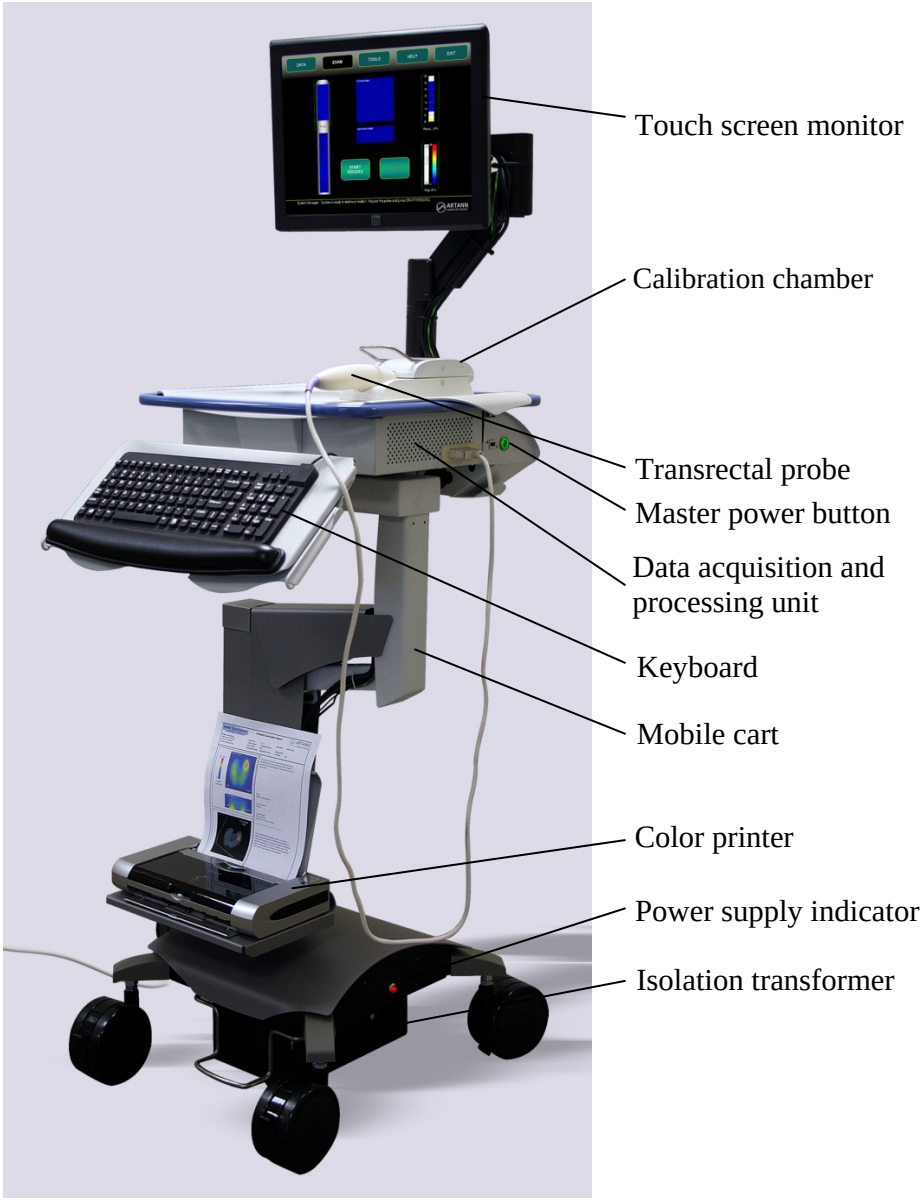
(10) a 510(k) cleared lubricating jelly to be applied to the sheathed probe; and

(11) a mobile cart.

The first pressure sensor array located at the tip of the probe is used to palpate the prostate. The second pressure sensor array located on the shaft of the transrectal probe shows the position of the probe relative to the sphincter, thereby providing an anatomical landmark helping to guide the probe manipulation. The motion tracking system built into the probe handle provides real time probe orientation data.

Hand-Held Transrectal Probe

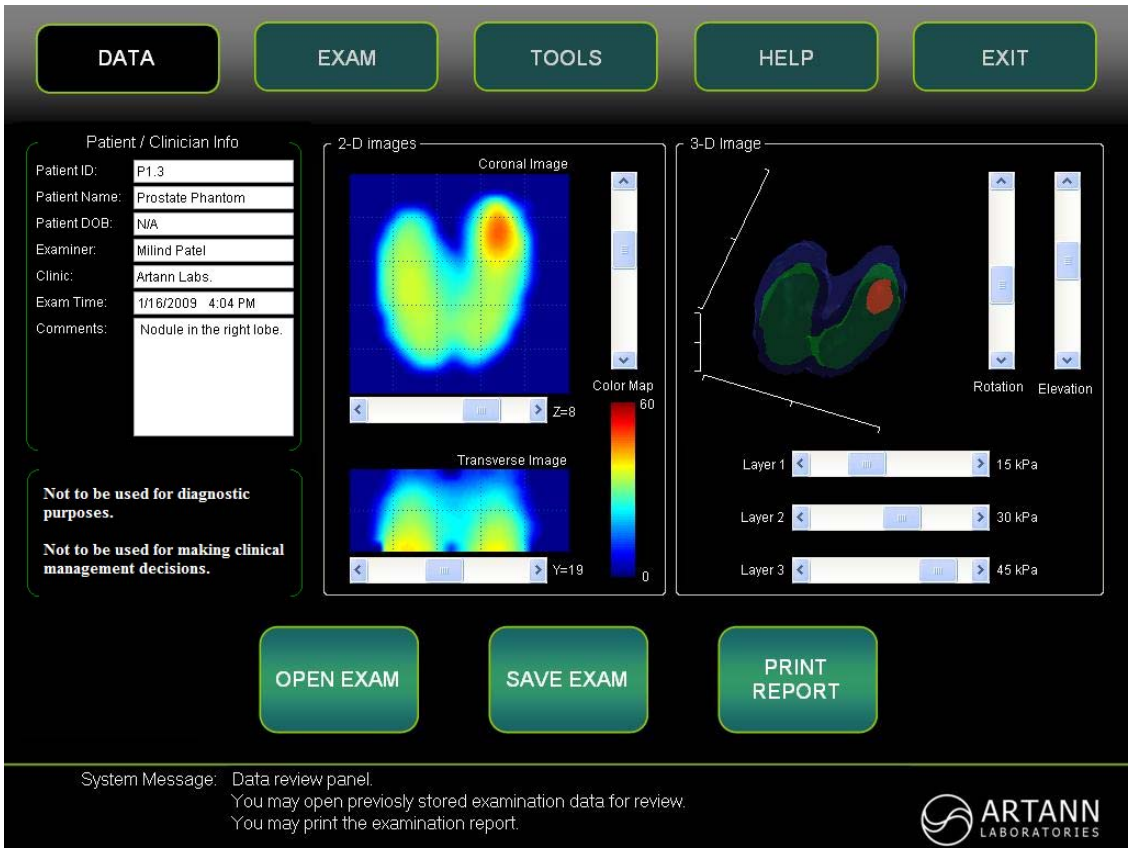
All components reside on the ergonomic mobile cart (pictured below) which also contains a medical grade isolation transformer to which all components are connected. There is a single power cord from this transformer that plugs into a standard electrical outlet.



PMI System Components on Mobile Cart

In order to perform the prostate procedure, the user must first place a disposable sheath on the end of the probe and apply a lubricant to the sheath. The tip of the probe is then inserted into the patient's rectum and the operator applies pressure with the probe tip while scanning over the prostate. As the prostate pressure patterns are being detected, a color image of the prostate is displayed on the computer monitor, along with an indication of the amount of pressure being applied to the probe. Procedure time is typically 1 minute, but up to 5 minutes.

The generated images show gradations in detected pressure (representing regional differences in prostatic tissue elasticity/hardness) by mapping to a range of colors, i.e., a color-coded elasticity image. For example, areas of the image depicted in deep blue represent the areas of tissue with the lowest firmness levels, progressing to higher firmness levels represented by the colors green, yellow, orange, and then red (highest firmness), in that order.



Sample of information displayed on LCD monitor, including 2-D and 3-D images

Description of Individual System Components:

Hand-Held Transrectal Probe

The PMI probe is ergonomically designed based on the rectal anatomy to minimize patient discomfort and to fit comfortably in the examiner's hand. The probe is equipped with two pressure arrays and a motion tracking system. The first pressure sensor array located at the head of the probe is used to palpate the prostate. The second pressure sensor array located on the shaft of the trans-rectal probe shows the position of the probe relative to the sphincter, thereby providing an anatomical landmark helping to guide the probe manipulation. The probe also has an off-the-shelf motion tracking system including a micro assembly of 3-D gyroscope, a 3-D accelerometer and a 3-D magnetometer built into the handle to provide real time probe orientation angles (elevation, azimuth and rotation). The orientation information in conjunction with the sphincter sensors information is used to map the probe location. The probe is intended and labeled for single use only.

Pressure Sensor Arrays
The first pressure sensor array located on the head of the probe consists of 8 by 16 capacitive sensors with the grid 2.0 mm by 2.0 mm. The second pressure sensor array consists of 3 by 16 capacitive sensors placed along the probe shaft. The dynamic range of the sensors (0-100 kPa) far exceeds that needed for the PMI functionality (0-60 kPa). The pressure measuring sensor is a capacitor with two electrodes separated by a matrix of air and molded RTV silicone rubber. This creates an air gap whose width and hence capacitance changes with externally applied surface pressure. The electrodes are excited by a low voltage AC signal (5 V). The orientation sensor provides information on the probe angular motion.

Each sensor is created by intersection of the orthogonal conductive strips. The capacitance of individual sensors is in the range of tens of picoFarads (pF) and the relative change of the capacitance under the 100 kPa pressure is over 5% of the range.

The sensors are calibrated by placing the probe into the calibration chamber and applying the pressure sequence: 0 kPa, 5 kPa, 10 kPa, 15 kPa, 20 kPa, 25 kPa and 30 kPa. The range of 0 - 30 kPa corresponds to the operational range for the pressure sensor arrays. The sensor signals corresponding to known pressure values (calibration data) are stored in a calibration file. To translate a pressure sensor signal into an actual pressure, PMI software uses a poly-linear function. It converts an incoming signal into a pressure value expressed in kPa using the calibration data. If the pressure signal value exceeds 30 kPa, linear extrapolation is used based on the last calibration data for 20 kPa, 25 kPa and 30 kPa. Estimated maximum error in sensor pressure readings due to the linear extrapolation of the calibration data into the extended range up to 60 kPa is about 5%, which was determined to be too low to have any significant impact on PMI image features because its level is lower than the average accuracy calculated during PMI performance bench testing.

Orientation Sensor (Motion Tracking System)
The 3-D orientation sensor used in the PMI system provides a full 360 degrees measurement range on three axes (elevation, rotation and azimuth) with the accuracy of ±1.0 degree and with the sample rate of 180 Hz. The 180 Hz sample rate for the output data for 3-D orientation sensor is sufficient for synchronization of the orientation data and pressure sensor data because the latter is acquired at much lower rate at 30 frames per second.

Probe Calibration Chamber
The calibration chamber is designed to test and calibrate the probe each time the PMI device is turned on. The calibration system includes a pressure chamber, an air pump, two air valves, an off-the-shelf air pressure sensor, and a printed circuit board with a microchip to provide its functionality. The pressure chamber becomes air-tight after its cover is securely closed with the probe inside. When the pump is activated it applies a known pressure measured by the air pressure sensor simultaneously to every sensor of the probe pressure sensor arrays.

Data Acquisition Unit
The data acquisition unit is designed for signal amplification, sampling, digital conversion, and transmission to the central processing unit. It is composed of a printed circuit board (PCB) that connects through a USB port to the central processing unit. A cable is used to connect the probe sensors and orientation sensors to the data acquisition unit. The data from the probe and orientation sensor are serialized into data packets by the central processing unit. A microprocessor on the data acquisition unit runs a scanning algorithm that selects analog channels via analog multiplexers and samples them with internal analog-to digital converter. The probe and orientation data packets are combined and sent to the host for processing. The USB supplies the power needs for the data acquisition unit.

Central Processing Unit with Proprietary Software
The central processing unit processes the digital data from the probe sensors using proprietary PMI software. The computer is used to acquire the prostate pressure response signals and to calculate and compose 3-D prostate elasticity images. Once the prostate scan is completed and a 3-D prostate image is composed, selected coronal and transverse 2-D cross-sectional prostate views can be displayed on the monitor. The system uses a mini PC with a Pentium T7200 2 GHz processor with 1 GB memory.

Touch Screen Monitor
The computer communicates with a 1024x768 pixel 15-inch LCD touch screen monitor that is attached by a movable arm to the top of the system cart and is used as the graphical user interface to control the PMI functionality and visualize the resulting prostate images.

Color Printer
The computer is connected through a USB port to an optional compact color printer. The printer produces color hard copies of the prostate examination report that includes prostate images.

Keyboard
A commercially available, water-resistant keyboard is provided to enable data input by the user.

Disposable Probe Sheath
A clear, non-sterile, disposable elastic polyurethane sheath is used to cover the probe before each calibration and prostate imaging procedure, protecting the sensor array on the probe head, the probe shaft, and the probe handle. 510(k)-cleared sheaths are provided with each PMI system, are labeled for single use only, and are available for reorder.

Disposable System Cover
A clear disposable system cover is used to cover the PMI system before each examination. The system cover protects the cart handles, monitor, and the working areas on the cart and keyboard. The cover is used during an exam to reduce the risk of cross contamination of the system. The cover is not patient contacting. The labeling provides reordering information and requires the user to dispose of the system cover after each use to help

reduce the possibility of cross contamination. System functionality and usability has been validated with the system cover in place.

Probe Lubricant
Bacteriostatic, non-allergenic, water soluble, sterile lubricating jelly is required to lubricate the probe sheath and body orifice to facilitate entry of the probe into the rectal cavity and to optimize sensor head translation to help ensure proper image generation. A 510(k)-cleared lubricating jelly is provided with the PMI system and is available for reorder.

Mobile Cart
A mobile cart is provided to enable the computer console, printer and associated hardware to be housed and moved if necessary from room to room. The mobile cart is a commercially available medical cart with adjustable height. The cart has an electronics enclosure that is used to house the electronics and PC components.

SUMMARY OF NONCLINICAL / BENCH STUDIES

Nonclinical performance data were provided or referenced to address the device's biocompatibility, electromagnetic compatibility, electrical, mechanical, and thermal safety, and software. In addition, bench testing was performed to assess the device's ability to visualize abnormalities and produce images showing elasticity differences in prostate phantoms in a pelvic simulator.

BIOCOMPATIBILITY
The only patient-contacting materials of the Prostate Mechanical Imager are the probe sheath and the probe lubricant, both of which are 510(k)-cleared devices. From a biocompatibility perspective, the cleared uses of these devices are consistent with their uses as part of the PMI system (i.e., direct mucosal contact for 1-5 minutes).

The type of tissue contact (rectal mucosa) and duration of contact (< 5 minutes) do not raise the level of biocompatibility concern relative to the cleared uses. Thus, the biocompatibility of the probe sheath and probe lubricant (i.e., sensitization, irritation, and cytotoxicity) has been demonstrated by the premarket clearance of these two patient-contacting PMI system components.

STERILITY / SHELF LIFE / REUSE
Other than the 510(k)-cleared probe lubricant, none of the PMI system components is sold sterile, and there are no components that are to be sterilized by the user. The 510(k)-cleared, disposable probe sheath is not provided sterile, and sterilization for this use is unnecessary because it is not being used in a sterile environment.

The system does not have a stated shelf life. Based on the nature of the system components (i.e., electrical and computer hardware, medical cart, printer, keyboard, monitor), the absence of a shelf life is acceptable.

The PMI probe, probe sheath, and system cover are all single-use disposable components. The PMI probe and probe sheath are considered semi-critical devices. Because these components are not labeled for reuse, validation of the reprocessing methods and instructions (including cleaning and high-level disinfection) was not necessary.
The electrical and computer hardware, calibration chamber, medical cart, printer, keyboard, and monitor are all reusable, non-critical components. To help mitigate the potential for cross-contamination between patients (e.g., due to the operator contacting the keyboard or touch-screen monitor with a soiled glove), a disposable system cover is used during the procedure and replaced afer each use.

ELECTROMAGNETIC COMPATIBILITY

The *de novo* includes adequate test reports and labeling to support the claim of conformity to IEC 60601-1-2 (edition 2.1, Amendment 1: 2004) *"Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard 2; Electromagnetic Compatibility – Requirements and Tests."* Immunity Tests included for IEC 60601-1-2 testing included the following collateral standards:

- Immunity Standards EN61000-4-2 (ESD)
- EN 61000-4-3 (Radiated Susceptibility)
- EN 61000-4-4 (EFT/Burst)
- EN 61000-4-5 (Surge)
- EN 61000-4-6 (Conducted Susceptibility)
- EN 61000-4-8 (Magnetic Fields)
- EN 61000-4-11 (Short Interruptions and Voltage Variations)

Test reports and labeling were provided demonstrating the PMI device's compliance with the above standards.

ELECTRICAL, MECHANICAL, AND THERMAL SAFETY

The device was tested to address compliance with the requirements of IEC 60601-1 (1998; Amendment 1 and Amendment 2) *"Medical Electrical Equipment – Part 1: General Requirements for Safety."* The *de novo* includes adequate test reports and labeling to support the electrical, mechanical, and thermal safety of the device. The results, with accompanying justifications, were determined to be sufficient to provide reasonable assurance of the PMI system's electrical, mechanical, and thermal safety.

SOFTWARE

The software for the Prostate Mechanical Imager presents a minor level of concern based on FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005). Considering the nature of the device and the limitations on its use (i.e., solely to be used as a documentation tool, not for diagnostic purposes or for influencing any clinical decisions, and not to be used as a replacement for digital rectal examination), there is no potential for a failure or design flaw in the software to result in injury, erroneous diagnosis, or a delay in delivery of appropriate medical care.

The PMI software provides data acquisition from the pressure and orientation sensors located in the probe and transforms the acquired data into 2-D and simulated 3-D prostate

elasticity images. Once the prostate examination is completed and a 3-D prostate elasticity image is composed, the user can select 2-D cross sectional views of the 3-D prostate elasticity image to document the details in a hard-copy color printout and/or electronically stored examination report. The PMI system software runs on a standard computer running Windows XP software platform with Microsoft .NET Framework.

Described at a high level, the primary functions of the PMI software are to:

1. Collect prostate examination data (pressure and orientation data),
2. Display the collected data,
3. Provide real time prostate images and 2-D prostate image construction,
4. Store the collected data and prostate image,
5. Document the prostate images,
6. Present the results of stored examinations, and
7. Generate a printed customizable report.

The *de novo* includes a device hazard analysis, which contains a tabular description of identified hardware and software hazards, including severity assessment and mitigation measures.

The sponsor's verification and validation testing documentation (PMI Software Test Plan and PMI Software Test Report) includes the following expected elements for a minor level of concern: functional test plan, pass/fail criteria, and summary of results. The documentation provides sufficient evidence that the specified requirements have been fulfilled.

All expected elements of software documentation (per *FDA's Guidance for Off-the-Shelf Software Use in Medical Devices; Final*, issued September 9, 1999, and *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff*) are included in the *de novo* and are in sufficient detail to provide reasonable assurance that the software performs as intended and all software-related risks have been adequately mitigated.

PERFORMANCE TESTING – BENCH

Performance of the device was initially designed and evaluated using soft tissue phantoms with a set of hard inclusions of different sizes prepositioned at different depths. The experiments demonstrated that the technology enabled detection of hard nodules.

The device's ability to image the prostate and detect areas of hardness was also addressed by a comparison of the device against manual palpation and pathology results on removed prostate glands in a 1998 published study. The study was performed in collaboration with the Robert Wood Johnson University Medical Center. Histological findings from all posterior segments of nine excised prostates were compared to PMI generated images of the gland. Study findings confirmed that all PMI depicted abnormalities correlated closely with the palpated nodules and pathology findings.

An anatomical model of the male pelvis with an anal canal, rectal wall, and interchangeable silicone models of the prostate gland was designed to accurately represent elasticity of real tissue. Several sets of prostate models of varied dimensions, shapes and elasticity, with structural inclusions mimicking nodules of various diameters and elasticity, were manufactured for the bench tests. Hard nodules were positioned in specific locations within the prostate models to simulate various prostate elasticity distributions. Performance testing was conducted (by 5 operators using 5 PMI systems on 24 prostate models, for a total of 720 examinations) to determine imaging accuracy, reproducibility over time, inter-system reproducibility, and inter-operator reproducibility for generating a real-time digital image. It was demonstrated through extensive bench testing that the PMI can reliably visualize abnormalities and produce images of nodules in prostate models in the pelvic simulator.

SUMMARY OF CLINICAL INFORMATION

In 2006, clinical testing of an earlier generation of the PMI device was conducted to study the factors affecting successful PMI image reconstruction capabilities. Following a standard DRE performed by an urologist, the PMI examination was conducted. The examiner was able to observe and inspect, in real-time, two orthogonal cross-sections of the prostate. The PMI scan data were saved in a digital format. As an outcome of this study, the PMI data were sufficient for image reconstruction of the prostate in 84% (141/168) of study cases. Based on a patient survey, the level of discomfort of the PMI was judged to be similar to that of a DRE examination.

In 2009, a clinical study was performed to test the imaging capability of the latest generation of the device by multiple users and to confirm that the incremental device modifications (introduced after the completion of the 2006 clinical study) did not negatively impact the performance and usability of the device. The main differences in the device are that the newer generation has a slightly smaller probe head, automated calibration of probe pressure sensors, and updated electronics. Five clinical investigators from five clinical sites collected PMI data for 56 clinical cases with prostate abnormalities detected by DRE. The following conclusions were derived from the study:

- PMI was shown to be capable of visualizing the prostate in 98% (55/56) of patients.
- There was agreement between DRE and PMI determinations regarding the presence of an abnormality in 89% of the studied cases.
- No safety concerns or side effects directly associated with the PMI examination procedure were found by any of the five clinical investigators participating in the study.
- All clinical investigators who participated in the study rated the PMI ease of use on a scale from 1 “not easy” to 5 “very easy”. The average score for all investigators participating in the study was 4.4.

LABELING

Labeling has been provided which includes instructions for use and a prescription use statement as required by 21 CFR 801.109. The labeling has been written to help ensure that sufficient

instructions are provided to limit the likelihood of (1) user error, (2) misinterpretation of displayed images, (3) failure to produce an accurate image, and (4) microbial contamination from reusable components.

The risk of user error is mitigated through labeling by including instructions stating that:

> The device is not to be used for any diagnostic purpose, as a replacement for digital rectal examination, or for making any clinical management decisions;
>
> The device is only to be used to image and document an abnormality that was already identified by DRE;
>
> Clinical management decisions are not to be made on the basis of information from the PMI device, but rather on the basis of the DRE. If there is disagreement between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., PSA levels) in accordance with standard medical practice;
>
> This device has not been shown to be effective in patients who have undergone prostate surgery, radiation therapy, cryotherapy, or chemotherapy for prior prostate cancer; and
>
> This device should not be used on patients with open wounds of the rectum or areas around the prostate, as this may increase the risk of tissue trauma, bleeding, and infection.

The risk of misinterpretation of displayed images is mitigated through labeling by including instructions explaining the meaning of the displayed colors and statements explaining that the images are not to be used for any diagnostic purpose or for making any clinical decisions.

The risk of failure to produce an accurate image is mitigated through labeling by including instructions explaining how to initialize the system and properly calibrate the probe prior to use, how to apply the proper amount of pressure to the probe head, how to redo the examination if the acquired image is not satisfactory, and when not to save and print the results (i.e., if the recorded images do not agree with the DRE findings).

The risk of microbial contamination from reusable components is mitigated through labeling by including instructions stating that the probe, probe sheath, and system cover are limited to single patient use; the reusable components are to be covered with the disposable system cover; a contaminated probe sheath must never be inserted into the calibration chamber; and specific reprocessing instructions must be followed.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a Prostate Lesion Documentation System and the measures recommended to mitigate these risks.

Identified Risk	Mitigation Measure
Failure to consistently produce an accurate image	Performance Testing (non-clinical and clinical); Software Verification, Validation, and Hazard Analysis Labeling
Misinterpretation of displayed images	Labeling
User error	Labeling
Microbial contamination from reusable components	Labeling Validation of Reprocessing Methods and Instructions
Adverse tissue reaction	Biocompatibility Testing
Electromagnetic incompatibility	Electromagnetic Compatibility Testing
Electrical injury	Electrical Safety Testing
Thermal injury	Thermal Safety Testing
Mechanical injury	Mechanical Safety Testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the Prostate Mechanical Imager is subject to the following special controls:

(1) Non-clinical and clinical performance testing must demonstrate the accuracy and reproducibility of the constructed image.

(2) Appropriate analysis/testing must validate electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety.

(3) Appropriate software verification, validation, and hazard analysis must be performed.

(4) All elements of the device that may contact the patient must be demonstrated to be biocompatible.

(5) Methods and instructions for reprocessing of any reusable components must be properly validated.

(6) The labeling must include specific information needed to ensure proper use of the device.

CONCLUSION

The *de novo* for the Prostate Mechanical Imager is granted and the device is classified under the following:

Product Code: OQT
Device Type: Prostate lesion documentation system
Class: II
Regulation: 21 CFR 876.2050