Augment Intelligent Medical System (China) Co., Ltd.
℅ Chen Lihong
Chief Clinical Application Officer
1801-1812, Floor18, Block B, Kechuang No.1 Building, No.320
Pubin Road, Jiangpu Sub-District, Pukou District
Nanjing, Jiangsu 211808
CHINA

November 22, 2022

Re: K221499
Trade/Device Name: Minimally Invasive Prostate Surgery Navigation System
(Model:AmaKris SR1-A-1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 20, 2022
Received: October 27, 2022

Dear Chen Lihong:

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. 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 located 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.

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

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 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
and Electronic Products
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)*
K221499

Device Name
Minimally Invasive Prostate Surgery Navigation System (Model:AmaKris SR1-A-1)

Indications for Use *(Describe)*
Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is intended for use by the trained physician or urologist to perform the computer-assisted prostate surgical procedures through transperineal skin under real-time transrectal ultrasound guidance. It provides the capability to register and fuse with MRI medical images in DICOM format. It provides real-time 3D visualization and localization for prostate, biopsy needle, and probe. It also provides the ability to display an image coordinates and guidewire that means the current and the projected future path of the biopsy needle. Other software feature include patient data management, prostate and tumor modeling, 3D image registration.

Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is intended for treatment planning and guidance for prostate surgical procedures in a clinical setting.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

K221499

Prepared Date: Oct 20,2022

Submitter's Information

The submitter of this pre-market notification is:

Name:	Augment Intelligent Medical System (China) Co., Ltd.
Address:	1801-1812, Floor 18, Block B, Kechuang No.1 Building, No.320 Pubin Road, Jiangpu Sub-District, Pukou District, Nanjing, Jiangsu 211808 China
Contact person:	Chen Lihong
Title:	Chief Clinical Application officer
E-mail:	chenlh@aimsrobots.com
Tel:	86-025-58600482

Device Identification

510(K) number:	K221499
Trade/Device Name:	Minimally Invasive Prostate Surgery Navigation System
Models:	AmaKris SR1-A-1
Common name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Regulation Name:	Picture archiving and communications system
Regulation Class:	Class 2
Panel:	Radiology
Product Code:	LLZ

Predicate Device

510(K) number:	K162474
Device Name:	Artemis
Manufacturer:	Eigen
Common name	System, Image Processing, Radiological
Regulation Number:	892.2050
Regulation Name:	Picture archiving and communications system
Regulation Class:	Class 2
Panel:	Radiology
Product Code:	LLZ

4. Indication for Use

Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is intended for use by the trained physician or urologist to perform the computer-assisted prostate surgical procedures through transperineal skin under real-time transrectal ultrasound guidance. It provides the capability to register and fuse with MRI medical images in DICOM format. It provides real-time 3D visualization and localization for prostate, biopsy needle, and probe. It also provides the ability to display an image coordinates and guidewire that means the current and the projected future path of the biopsy needle. Other software features include patient data management, prostate and tumor modeling,3D image registration.

Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures.

5. Device Description

To help physician or urologist to perform needling procedures on prostate, AmaKris SR1-A-1 serves as a needle guide, which enables the needling procedures safer, faster and more precision with lesser side effects such as infection and internal hemorrhage.

AmaKris SR1-A-1 is a computer-assisted medical device 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. Different from the conventional hand-held probe guidance and operator-dependent manual biopsy targeting, AmaKris SR1-A-1 is a platform-hosted motorized device integrating a probe-driving system for 3D image collection and a precise biopsy guidance mechanism (biopsy needle platform) to control the orientation of needle insertion and depth of puncture. This system is intended to be used with adult patients.

The device has a graphics user interface (GUI) that can provide a complete view of the 3D prostate to the physicians. The system allows users to draw contour curves of the organ/tumor referring to the transversal images, then the software performs contour fitting and generates the 3D model, based on which the prostate volume is calculated, and the systematic biopsy plan is made. 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.

The device is intended for use by a trained urologist or physician to perform the computer-assisted transperineal prostate biopsy under transrectal ultrasound guidance. It shall be used in conjunction with a third-party ultrasound machine and endorectal probe that supports type-B ultrasound, and a third-party prostate biopsy gun and needle. The device services as a biopsy needle guide only. The insertion of biopsy needle will be done by the urologist.

AmaKris SR1-A-1 is composed of two modules:

Navigation Manipulator

Navigation manipulator is a computer-controlled surgical manipulator. There are 3 servo motors controlled by both magnetic encodes and potentiometers to provide higher position accuracy and quick location responses. A nine axes Inertia Measurement Unit (IMU) has been integrated into this system to measure the movement of pitch, yaw, rotation and acceleration.

Intelligent Surgical Console

The intelligent surgical console is the core platform of the system, the software operating platform for medical imaging processing, biopsy planning and execution, as well as a mobile platform for surgery. The intelligent surgical console has a built-in IPC, on which runs the AmaKris software. The software acquires real-time ultrasound images from the ultrasound diagnostic apparatus and controls the navigation manipulator. The navigation manipulator is a portable device for prostate biopsy execution. It is fixed into the intelligent surgical console and controlled by the intelligent surgical console. The intelligent surgical console is consisted of main components including the base, main body, mobile surgical table, and touch screen monitor.

6. Compared to Predicate Device

The design, function, and specifications of AmaKris SR1-A-1 are similar to the identified legally marketed predicate devices Artemis (K162474). AmaKris SR1-A-1 and Artemis (K162474) similarly provide image-guided interventional planning and navigation for prostate procedures, the ability to view and capture live 2D ultrasound data to create reconstructed 3D ultrasound images/models, and the ability to fuse and register these images with the images acquired and imported from other modalities like Magnetic Resonance Imaging, and Ultrasound.

AmaKris SR1-A-1 and Artemis (K162474) also similarly perform other viewing and image-processing functions such as image registration, multi-planar reformats and includes tools to segment, measure and annotate images. AmaKris SR1-A-1 and Artemis (K162474) can import data from other DICOM based imaging devices and also output selected image views, processed data and user-defined reports.

AmaKris SR1-A-1 and Artemis (K162474) similarly utilize a mechanical arm with encoders to determine the location of the ultrasound probe.

The main difference between AmaKris SR1-A-1 and Artemis (K162474) is the physical form. This difference does not impact device safety or effectiveness.

Other differences between AmaKris SR1-A-1 and Artemis (K162474) include minor user interface variations such as GUI icons, screen colors and image viewing layouts. These differences are cosmetic in nature do not significantly affect the use of the device, nor do they raise new or additional safety risks. These differences between AmaKris SR1-A-1 and the legally marketed predicate device do not impact device safety or effectiveness.

AmaKris SR1-A-1 is a diagnostic and interventional software accessory to perform the computer-assisted prostate surgical procedures through transperineal skin under real-time transrectal ultrasound guidance. It provides convenient options for visualizing diagnostic and interventional information in support of routine clinical procedures of the prostate gland. The device does not directly contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the AmaKris SR1-A-1 system but by Radiologists, Urologists, Clinicians and referring Physicians.

A physician, providing ample opportunity for competent human intervention interprets the images and information being displayed and maintains control of the clinical procedure at all times.

The AmaKris SR1-A-1 utilizes the same technological characteristics as the predicate devices Artemis (K162474).

Both:

- are PC based software applications that provide 2D and 3D medical image acquisition including ultrasound video image acquisition arid visualization of the prostate gland
- use Windows operating systems
- allow registration of live ultrasound images to previously created 3D image sets based on previously collected ultrasound image sets or DICOM images sets
- include image enhancements such as zoom and pan capabilities
- provide patient and clinical data management features
- deal with live ultrasound images received from commercially available imaging devices.
- use graphic overlays to define segmentations
- calibrate ultrasound 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
- are only intended for use on the prostate gland
- utilize a mechanical arm with encoders to determine the location of the ultrasound probe.

Compared to the predicate devices, the subject device has the same intended use, similar product design, similar performance, same safety as the predicate device, the summarized comparison information is listed in the following table

SE Comparisons	**Proposed Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1)	**Primary Predicate Device** Artemis (K162474)	**Similarities/ Differences**
Indication for Use	Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is intended for use by the trained physician or urologist to perform the computer-assisted prostate surgical procedures through transperineal skin under real-time transrectal ultrasound guidance. It provides the capability to register and fuse with MRI medical images in DICOM format. It provides real-time 3D visualization and localization for prostate, biopsy needle, and probe. It also provides the ability to display an image coordinates and guidewire that means the current and the projected future path of the biopsy needle. Other software features include patient data management, prostate and tumor modeling,3D image registration. Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures.	Artemis along with the Needle Guide Attachment is used 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 Ultrasound, Magnetic Resonance, Computed Tomography, etc. It also provides the ability to display a simulated image of a tracked insertion tool such as a biopsy needle, guidewire 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 patient movement into account. The software also provides a virtual grid on the live ultrasound for performing systematic sampling of the target organ. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements, 2D/3D image registration, reporting, and pathology management. Artemis 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,	The main function of the subject device and predicate device is that help doctor conduct biopsy of prostate by providing real-time 3D visualization and localization for prostate, biopsy needle, and probe.

SE Comparisons	**Proposed Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1)	**Primary Predicate Device** Artemis (K162474)	**Similarities/ Differences**
		soft tissue biopsies, soft tissue ablations and placement of fiducial markers. Artemis is also intended to be used for patients in active surveillance to keep track of previous procedures information and outcomes.	
Product code	LLZ	LLZ	Same
Class	II	II	Same
Target anatomy	Prostate	Prostate	Same
Anatomy access	Transperineal	Transrectal & Transperineal	The subject device only provides Transperineal needle guidance procedures. There is no risk raise.
Software			
Windows OS	Yes	Yes	Same
Medical Imaging Software	Yes	Yes	Same
Image display			
General Image 2D/3D Review	Yes	Yes	Same
3D Rendering View	Yes	Yes	Same
Live 2D Ultrasound	Yes	Yes	Same
Image Process			
Gland Segmentation	Yes	Yes	Same
Image Registration	Yes	Yes	Same
Rigid Registration	Yes	Yes	Same
Elastic Registration	Yes	Yes	Same

SE Comparisons	**Proposed Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1)	**Primary Predicate Device** Artemis (K162474)	**Similarities/ Differences**
Multi-Planar Reformation	Yes	Yes	Same
Connectivity			
DICOM Import/Export	Yes	Yes	Same
Ultrasound Video	Yes	Yes	Same
Review Tools			
Standard Image Viewing Tools	Yes	Yes	Same
Measurement Tools	Yes	Yes	Same
Annotation Tools	Yes	Yes	Same
Segmentation Tools	Yes	Yes	Same
Reporting Tools	Yes	Yes	Same
Video Capture	Yes	Yes	Same
Image Overlays	Yes	Yes	Same
Planning & Navigation			
Import Prior Plan	Yes	Yes	Same
Import/Add Targets	Yes	Yes	Same
Plan/Mark Locations	Yes	Yes	Same
Navigation Type	Mechanical	Mechanical	Same

The new device and predicate devices are substantially equivalent in the areas of technological characteristics such as basic design, features, energy source, method of operation, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

8. Performance Data

Clinical test:

Clinical testing is not required.

Safety and Effectiveness

The AmaKris SR1-A-1 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 Risk Management procedure, which is used to identify potential hazards. These potential hazards are controlled via the product (software and hardware) development process, verification and validation testing.

Non-clinical data

-Safety

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

-EMC

IEC 60601-1-2:2014 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic Disturbances-Requirements and tests

-Software Verification and Validation:

FDA software validation guidance “General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002”.

Software documentation for moderate level of concern per the FDA Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Performance Testing:

- Verification of Accuracy and Precision

In the test, a needle pen is designed as such a pen refill is secured to the needle sheath guide and then inserted to the end effector of the manipulator. A template is created on a piece of target sheet. The template consists of 25 target circles, each of which consists of three concentric circles with radius of 0.5mm, 1.0mm, and 1.5mm, respectively, with the target point as the center of the circle. There are a total of 5 different patterns to verify the accuracy and precision of various movement mode.The navigation system of the device will guide the manipulator from the home position P0 to the designate target position. The manipulator will move through a series of position patterns preset by the software.

Based on the raw data, we used SPSS 16.0 analysis software to analyze the positioning accuracy and precision of each testing point on the target sheet. The analysis results shows that the total number of sample points tested is 325, and the mean value of the overall positioning accuracy is 0.404 (mm) with the mean value of total variance 0.2243, which means the positioning accuracy is within 1.0 mm radius and meets the biopsy specification.

In addition, it was analyzed whether the positioning accuracy was influenced by the position of target points or the moving pattern of the end effector of the manipulator. The analysis method used was a two-factor ANOVA model. The results show that the P-values of the tests for the effects of the position of target points and the moving pattern of the end effector of the manipulator are less than 0.001, indicating that both are statistically significant. The positioning accuracy is higher in the lower left region of the target sheet (with lower deviation value from the target), and lower in the upper right corner and the rest of the outer boundary of the target sheet. The positioning accuracy is higher for moving pattern 1 and 2 and lower for moving pattern 3 and 4.

-Simulation Testing for Verifying Accuracy and Precision

a. Egg Phantom Test

A shelled hard-boiled pigeon egg was used to simulate the shape, size, and texture of human prostate. The egg was suspended in gelatin to allow for conductance to ultrasound waves. The container was a transparent plastic cylindrical box.

The standard protocol began with the acquisition of the ultrasound images of the suspended egg. After delineation of its margins, a 3D model is generated by the software to be verified. In target planning, the tester identified eight random target points, with two in each quadrant within the egg boundary. The software did not allow placement of any target points outside the verified 3D model, which was consistent with the clinical safety requirements defined by the urologists. The test goal is to observe whether the directional needle is outside the egg. According to the test, all punctures on eight random target points for three cycles are placed inside the egg boundary. This test verified that the device system is able to navigate biopsy needles to targets within a defined boundary.

b. Metal Needle Phantom Test

Prepare the gelatin phantom box as described previously without the egg. The top surface of the box has 16 puncture sites spaced in 10 mm matrix for inserting the metal needles. The box is placed where the nearest row of puncture sites is 99 mm from the needle holder on the guider. 16 metal needles with a diameter of 1 mm be inserted in sequence from the top surface of the box perpendicular to the ultrasound probe, whose tips randomly placed within a radius of 2-5 cm of the center of the ultrasound probe. Set the area to be where the prostate is normally located and within the detection range of the ultrasound. After the ultrasound images were collected, the metal needle tip (target points) was identified by the software. A marker was placed at the point of the metal needle tip shown on the software planning screen to guide the navigation system to that position. Next, the biopsy needle was inserted through the needle sheath until the biopsy needle tip reaches the position of the metal needle tip in longitudinal depth. Measure and recorde the distance (mm) between the biopsy needle tip to the mental needle tip with the electronic vernier calipers. Same procedure was repeated for all metal needles. To validate repeatability, the biopsy needle was returned to each

position of all metal needle tips for a total of 5 times with the same methods of measurement.

Based on the raw data, we used SPSS 16.0 analysis software to analyze the accuracy and precision of robotic-navigated puncture under TRUS guidance was analyzed by experimental data of the distance between the biopsy needle tip and the metal needle tip (target point). The mean value of the distance of the two needle tips is 0.435 mm, the mean variance is 0.1903, and the total number of punctures is 80.

In addition, the mean value of the distance between the biopsy needle tip and the metal needle tip (target point), which shows the navigation accuracy of the device, was further analyzed to see if it was influenced by the position of the target point. The analysis method used was a one-way ANOVA model.The results showed that the P-value for the test of the position effect was less than 0.001, indicating statistical significance. The closer the target point position to the needle holder on the guider, the higher the navigation accuracy is, and the farther the target point position to the needle holder on the guider, the lower the navigation accuracy is.

- Verification of Accuracy and Precision of Model Fusion

Selected 18 typical directions of divergence from the O-point (with serial number 1 to 18), the center of mass of the fusion model, for testing, including 8 target directions along the Z-axis; 6 target directions along the X-axis that do not coincide with the Z-axis direction; and 4 target directions along the Y-axis that do not coincide with the Z- and X-axis directions.

The distances between the O points in these 18 directions and the intersection points on the surfaces of the MRI model and ultrasound model, were measured with the software, and the accuracy and precision of the model fusion were statistically analyzed on this basis.

Based on the raw data, we used SPSS 16.0 analysis software to analyze the accuracy and precision of model fusion, according to the analysis of 4 cases, the mean value of the distance is 1.2801 mm with a mean variance 0.92556. Furthermore, the difference of target direction does not have statistically significant effect on model fusion accuracy.

9. Conclusion

The 510(k) Pre-Market Notification for Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) contains adequate information, data, and nonclinical test results to enable FDA-CDRH to determine substantial equivalence to the predicate device. We have determined that our device, Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1), is substantially equivalent to the identified predicate device Artemis (K162474). A comparison with the legally marketed predicate device indicates that it is substantially equivalent to this device, and that it does not raise any new safety or efficacy concerns. new safety or efficacy concerns. The results of

comparing the intended use, function, technological characteristics, mode of operation, and specifications of Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) with the predicate devices demonstrate that Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) is substantially equivalent to predicate device Artemis (K162474).