September 11, 2025

Augment Intelligent Medical System (China) Co., Ltd.
Yongwei Wang
COO
1801-1812, Floor 18, Block B, Kechuang No.1 Building, No.320
Pubin Road, Jiangpu Sub-District, Pukou District
Nanjing, Jiangsu 211808
China

Re: K242314
Trade/Device Name: Minimally Invasive Prostate Surgery Navigation System(Model:AmaKris SR1-A-2)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 29, 2025
Received: July 29, 2025

Dear Yongwei Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
DHT8B: Division of Radiological
Imaging and Radiation Therapy Devices
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)*
K242314

Device Name
Minimally Invasive Prostate Surgery Navigation System(Model:AmaKris SR1-A-2)

Indications for Use *(Describe)*
Minimally Invasive Prostate Surgery Navigation System(Model:AmaKris SR1-A-2) is intended to guide trained urologists in the planning and positioning of insertion tools during the performance of trans-perineal prostate biopsies and interventional procedures under trans-rectal biplane ultrasound guidance. The procedures include clinical diagnosis and treatment of prostate conditions: biopsy, single or multi-needle ablation, and particle implantation.
The device provides real-time 2D ultrasound scanning of the prostate to construct a 3D model and fuses it with the MRI 3D model, which can assist the surgeon in planning the puncture path avoiding the urethra and pubic bones. The device also provides a 3D simulation showing the current and planned puncture path of insertion tools such as biopsy needle and therapeutic needle, taking into account patient movement.

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.

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: September.11,2025

Submitter's Information

The submitter of this pre-market notification is:

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Device Identification

510(K) number:	K242314
Trade/Device Name:	Minimally Invasive Prostate Surgery Navigation System(Model: AmaKris SR1-A-2)
Common name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Regulation Name:	Medical image management and processing system
Regulation Class:	Class 2
Panel:	Radiology
Product Code:	LLZ

Predicate Device

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

4. Indication for Use

Minimally Invasive Prostate Surgery Navigation System(Model: AmaKris SR1-A-2) is intended to guide trained urologists in the planning and positioning of insertion tools during the performance of trans-perineal prostate biopsies and interventional procedures under trans-rectal biplane ultrasound guidance. The procedures include clinical diagnosis and treatment of prostate conditions: biopsy, single or multi-needle ablation, and particle implantation.

The device provides real-time 2D ultrasound scanning of the prostate to construct a 3D model and fuses it with the MRI 3D model, which can assist the surgeon in planning the puncture path avoiding the urethra and pubic bones. The device also provides a 3D simulation showing the current and planned puncture path of insertion tools such as biopsy needle and therapeutic needle, taking into account patient movement.

5. Device Description

Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-2) is a clinical device that integrates computer technology, medical imaging technology, navigation technology and robot technology. It can be used to guide surgeons in the planning and positioning of insertion tools (e.g., biopsy needles, therapeutic needles, etc.) during trans-perineal prostate diagnostic and interventional procedures with the guidance of MRI and ultrasound (MRI-TRUS) fusion.

The device allows the importation of multi-parameter MRI images to construct 3D models of the prostate, tumor, urethra, and pubis. It can also construct 3D models based on real-time images from commercial ultrasound system, and provide the fusion between ultrasound and MRI 3D models as the guidance and visualization references for prostate biopsy and interventional procedures. The insertion of biopsy needles or therapeutic needles is performed manually by the surgeon. Other software functions include patient data management, multi-planar reconstruction and segmentation, image measurement, surgical planning, and report generation.

AmaKris SR1-A-2 is composed of two modules: Navigation robotic arm and Intelligent Surgical Console.

The device is used in conjunction with a commercial urological ultrasound device supplied by the hospital. The third-party ultrasound system is composed of a beamformer and a bi-plane transducer (probe) with a linear array and a convex array. The beamformer is connected to AmaKris SR1-A-2's IPC by a USB cable and is powered by a 12V power supply cable. AmaKris SR1-A-2 receives the image signal through the driver software provided by the ultrasound manufacturer and displays it on the screen.

6. Modifications between AmaKris SR1-A-2 and AmaKris SR1-A-1

a. Add an IFU claim to state a new function for planning and navigation of interventional procedures, such as soft tissue ablations.

b.Software update: add ablation plan and puncture function.

c.Navigation robotic arm's construction was upgraded.

d.Navigation robotic arm parameters were modified.

e.Add a Robotic arm bracket,which can lower the working height of the navigation robotic arm and expand the operating space.

f. Modeling algorithm was upgraded.

g. AmaKris SR1-A-2 needs to be used in conjunction with recommended models of ultrasound equipment, SmartUs EXT-1M/3M(K163121) .

f. Other minor changes,sucn as IPC configuration upgrade,software UI upgrade, These changes do not significantly affect the use of the device, nor do they raise new or additional safety risks.

7. Compared to Predicate Device

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	**Subject Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-2)	**Predicate Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) K221499	**Similarities/ Differences**
Indication for Use	Minimally Invasive Prostate Surgery Navigation System is intended to guide trained urologists in the planning and positioning of insertion tools during the performance of trans-perineal prostate biopsies and interventional procedures under trans-rectal biplane ultrasound guidance. Types of procedures include, but are not limited to, clinical diagnosis and treatment of prostate conditions such as: biopsy, single or multi-needle ablation, and particle implantation, etc. The device provides real-time 2D ultrasound scanning of the prostate to construct a 3D model and fuses it with the MRI 3D model, which can assist the surgeon in planning the puncture path avoiding the urethra and pubic bones. The	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.	The subject device claims a new function for planning and navigation of interventional procedures. However,its work principle and operation process are the same.

SE Comparisons	**Subject Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-2)	**Predicate Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) K221499	**Similarities/ Differences**
	device also provides a 3D simulation showing the current and planned puncture path of insertion tools such as biopsy needle and therapeutic needle, taking into account patient movement.	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.	
Product code	LLZ	LLZ	Same
Class	II	II	Same
Target anatomy	Prostate	Prostate	Same
Anatomy access	Transperineal	Transperineal	Same
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
Multi-Planar Reformation	Yes	Yes	Same
Connectivity			
DICOM Import/Export	Yes	Yes	Same
Ultrasound	Yes	Yes	Same

SE Comparisons	**Subject Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-2)	**Predicate Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) K221499	**Similarities/ Differences**
Video			
Connect to ultrasound device	be used in conjunction with recommended models of ultrasound equipment, SmartUs EXT-1M/3M (K163121) .	be used in conjunction with a third-party ultrasound machine and endorectal probe that supports type-B ultrasound	Different. Only specified device can be used with the subject device.
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
Hardware			
Navigation robotic arm	comprises guider,control arm and support arm	comprises guider,manipulator, moving arm and rotating arm.	Different. The construction was modified.

SE Comparisons	**Subject Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-2)	**Predicate Device** Minimally Invasive Prostate Surgery Navigation System (Model: AmaKris SR1-A-1) K221499	**Similarities/ Differences**
Robotic arm bracket	With	Without	Different. It can lower the working height of the navigation robotic arm and expand the operating space.
Accessory & Disposable	Medical ultrasonic coupling agent, biopsy needle/gun, coaxial guiding needle, ablation needle, particle implantation gun/needle, interventional needle, probe cover, rubber band, adhesive tape, sterile probe sleeve and device protective cover	Medical ultrasonic coupling agent, biopsy needle/gun, needle sheath, anal dilator, condom, rubber band, duct tape, disposable plastic probe cover and protective cover.	Different.

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-2 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

The following testings were conducted on the subject device AmaKris SR1-A-2.

- Safety test were conducted according to IEC 60601-1:2005+AMD1:2012+AMD2:2020.

- EMC testings were conducted according to IEC 60601-1-2:2014+A1:2020.
- Verification of Accuracy and Precision:

  Method: 25 Points Test

  Acceptance criteria: Mean Deviation⩽2.1 mm,Standard Deviation ⩽1.3 mm

  Results: the total mean of the target point puncture precision was 0.397 mm, and the mean variance was 0.2043.
- Simulation Testing for Verifying Accuracy and Precision:

  Method: a. Egg Phantom Test b. Metal Needle Phantom Test

  Acceptance criteria: Mean Deviation⩽2.1 mm, Standard Deviation ⩽1.3 mm

  Results: The test results showed the device system is able to navigate puncture needles to targets within a defined boundary. The average navigation accuracy is 0.435mm with a mean standard deviation of 0.1903, which means the navigation accuracy is within 1.0 mm radius
- Model Fusion Accuracy and Precision verification

  Method: used ICP (Iterative Closest Point) algorithm for model fusion.

  Acceptance criteria: Mean Deviation ⩽2.4mm,Standard Deviation ⩽1.2 mm

  Results: According to the analysis of 4 cases, the mean value of the distance between A and B is 1.4270 mm with a mean standard deviation 0.86617. Furthermore, the difference of target direction does not have statistically significant effect on model fusion accuracy.
- Software Verification and Validation: To ensure all software updates meets the specifications and the intended purpose.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicated device (K221499).